BANNED & BANNABLE DRUGS

Unbiased Drug Information Essential Drugs and Rational Drug Policy

5th Revised Edition

Voluntary Health Association of India

Voluntary Health Association of India (VHAI)

VHAI is a non profit making, non-government organization, coordinating the health activities of over 4000 health institutions all over the country.

VHAI is committed to social justice in health care. This commitment is reflected in its training programmes and the production of educational material. VHAI is the biggest distributor of low cost relevant health education material in the Third World.

VHAI's involvement with the drug issue has been its response to the increasing commercialization and pharmaceuticalization of health care. VHAI has been deeply concerned about the increasing misuse of drugs, non-availability of essential drugs, non-availability of unbiased drug information and poor drug controls and legislation.

VHAI has for several years been endeavouring to ensure that India's National Drug Policy is rational and people oriented. It has also endeavoured to reach out to consumers and health personnel to make them more drug conscious. VHAI is part of the Health Action International Network of like-minded organizations across the world fighting for Rational Drug Use.

The book is a VHAI contribution to the efforts towards a Rational Drug Policy and Rational Drug Use.

To Gopal
In solidarity.
Mira

Banned and Bannable Drugs

Unbiased Drug Information
Essential Drugs
and
Rational Drug Policy

Dr. Mira Shiva, M.D.
and
Dr. Wishvas Rane

Brought out in Public Interest
By

Voluntary Health Association of India
B-40, Qutab Institutional Area
New Delhi

Foreword

The human right of every individual to health implies that when persons are unwell they would receive treatment which is up to date and be prescribed medicines which are effective and safe. Dr. Mira Shiva and Dr. Wishvas Rane's book shows us how difficult this is in a country where doctors have access to medicines which legally should not be available in the country since these are banned and many other medicines which should have been banned have not been banned and are available for use. This depressing scenario is compounded by the fact that medicines, even powerful antibiotics, are available without prescription, that pharmacies do not always have a pharmacist, that fake or substandard medicines are circulating in the country and irrational prescribing is rampant and one could see why the patient is exposed unnecessarily, unethically and inequitably to the hazards of medicines. Medicines are but a tool – these could be a boon or could spell the doom of many patients. The statistics suggest that between 5% to 15% of admissions to hospitals are due to the side effects and toxicity of medicines and not due to any disease. The figure is much higher in elderly persons. All these issues have been discussed in the very masterly and objective Introduction to the book by the authors.

This volume is the fifth edition of Banned and Bannable Drugs which was first published in 1986. Some of facts mentioned in the book are chilling. The authors say that 23 out of the top selling 80 products in the country are either irrational or hazardous or both. It is very clear that the World Health Organization programme in rational use of medicines in India would have succeeded to a much longer extent had the country get rid of the banned drugs so that these were not available, if the office of the Drugs Controller General had been expanded strengthened and made more effective and if the existing laws been implemented in a more effective manner.

The authors of this book are to be congratulated for having provided an up to date, evidence based tool to the people to protect themselves against the toxic effects of medicines by trying to find out for themselves if the medicines prescribed to them or sold to them are in the banned list of medicines. The book is an effective tool to empower the public to look after their health better. If the state and governance of the state are unable to provide protection to its citizens they have to take measures to protect themselves. They cannot do so unless they have information and knowledge. This excellent books provides both. The section under "Consumer Action" details thirty three steps which the consumer should take to protect themselves and others.

The book gives a list of drugs which have been banned in other countries – listing

these countries, but which are available in this country. It gives an objective write up clearly stating what side effects are induced by the drug, which safer alternatives are available and which pharmaceutical houses are producing this medicine in India. The information provided is clear and the documentation provided excellent. It is a book which should be within the reach of all practitioner/s of medicine so that they prescribe medicines better. It should, of course be read by the consumer of drugs and by all who are trying to implement rational use of medicines in the country. Rational Use of Drugs promotes not only better therapeutics by preventing side effects and interactions of medicines but it also saves money wasted today by the people who can ill afford to do so by purchasing unnecessary medicines and by purchasing banned and bannable drugs.

Prof. Ranjit Roy Chaudhury
President
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Coordinator – India WHO Essential Drugs Programme in Essential Medicines
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Preface

Like many areas of development policy, India took a lead in bringing out with an extra-ordinarily progressive report on Drug Policy, popularly known as Hathi Commission Report. In the ensuring years, many Governments and countries in south like Bangladesh have taken inspiration from this report to set up alternative Drug Policies in their own countries. But the Drug Policy in India had not been able to meet the challenges of acute needs of the patients, medical and health professionals with the backdrop of new economic policy and the process of globalization.

The book, "Banned and Bannable Drugs" has been a major weapon in the hands of drug activists of India. The revised version is being published to further add to the motivated struggle of numerous groups against this anti-people, anti-health Drug Policy. We hope that the document will receive the attention that it deserves from the planners, policy makers, medical professionals and voluntary organizations. Our fond hope is that India will ultimately inherit a sensitive Drug Policy, meeting the needs of its people substantially and showing the way to other developing countries.

Alok Mukhopadhyay
Chief Executive
Voluntary Health Association of India

Banned and Bannable Drugs
Unbiased Drug Information
Essential Drugs and Rational Drug Policy

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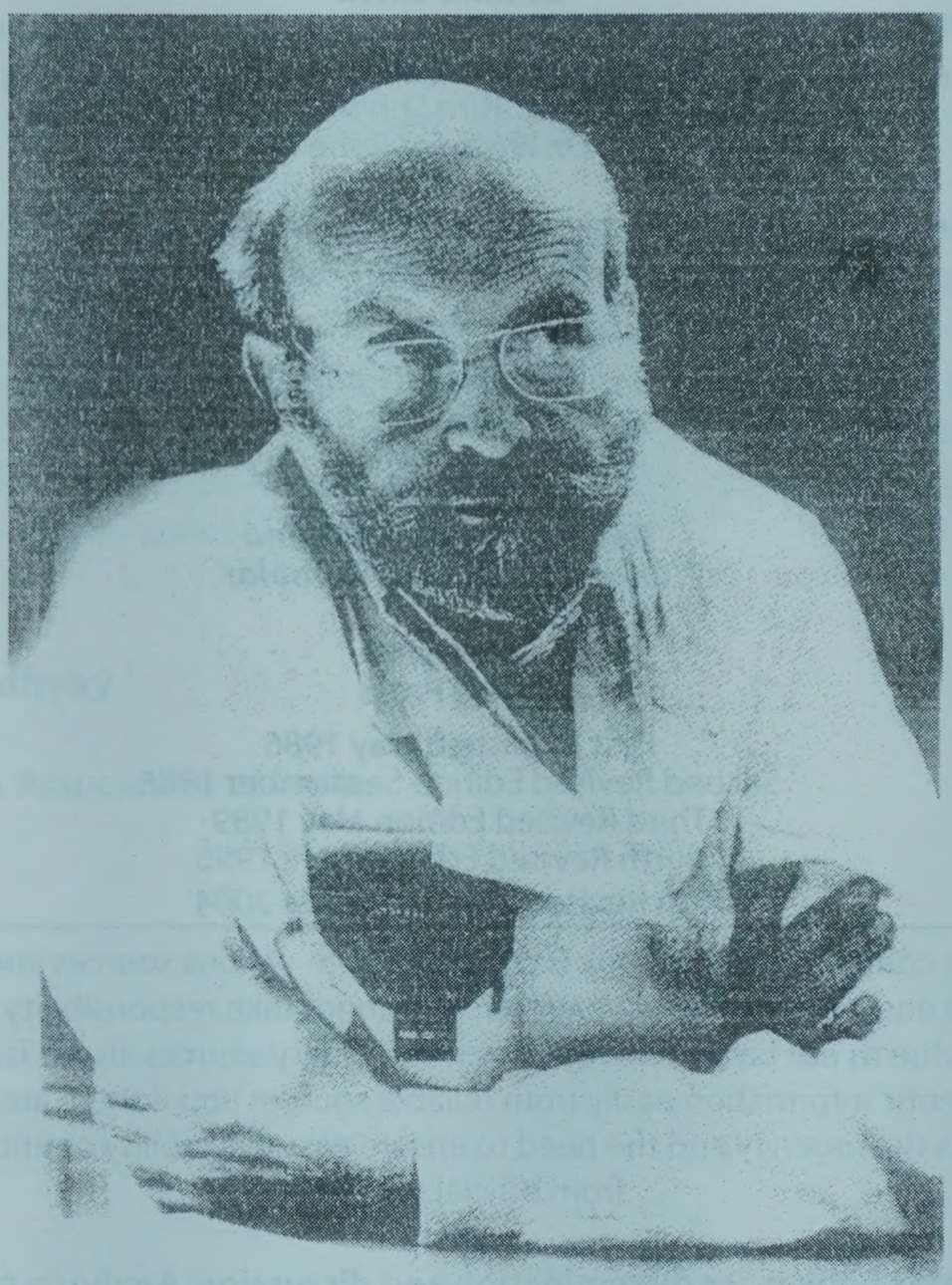
We Dedicate This Effort to the Memory of



Late Dr. Olle Hansson

One of the greatest health campaigners of our time, who believed in the patient's right to information, and firm adherence to medical ethics, who passed away on May 24, 1985.

Late Dr. Olle Hansson

Dr. Olle Hansson was a Swedish paediatric neurologist based in Gottenberg. His name is closely linked with his fight against Clioquinols (Mexaform-like drugs). Not merely did he provide scientific proof, about absorption of the drug, from the gut, when ingested, (even when this was being systematically denied) but he was the first to report blindness associated with the drug. Dr. Olle Hansson wrote in scientific medical journals and in the lay press persistently for several years, warning the medical community and consumers about drug related hazards.

He stood as an expert witness in Tokyo District Court on behalf of the SMON (Subacute Myelo Optic Neuropathy) victims and their relatives – to support their fight for compensation against the giant multinational, Ciba-Geigy.

He fought a long, lonely battle against needless, drug induced suffering, and for "the patient's right to information".

Affected with cancer, he continued his fight against the Swiss giant Ciba-Geigy to ensure withdrawal of Mexaform, Enterovioform and Butazones. (Oxyphenbutazone, Phenylbutazone) – publishing information related to deaths and disability of over thousands after consuming these drugs.

Dr. Olle Hansson had all the elements of a great health campaigner – scientifically sound facts and arguments, persistence and perseverance, honesty and integrity coupled with humility.

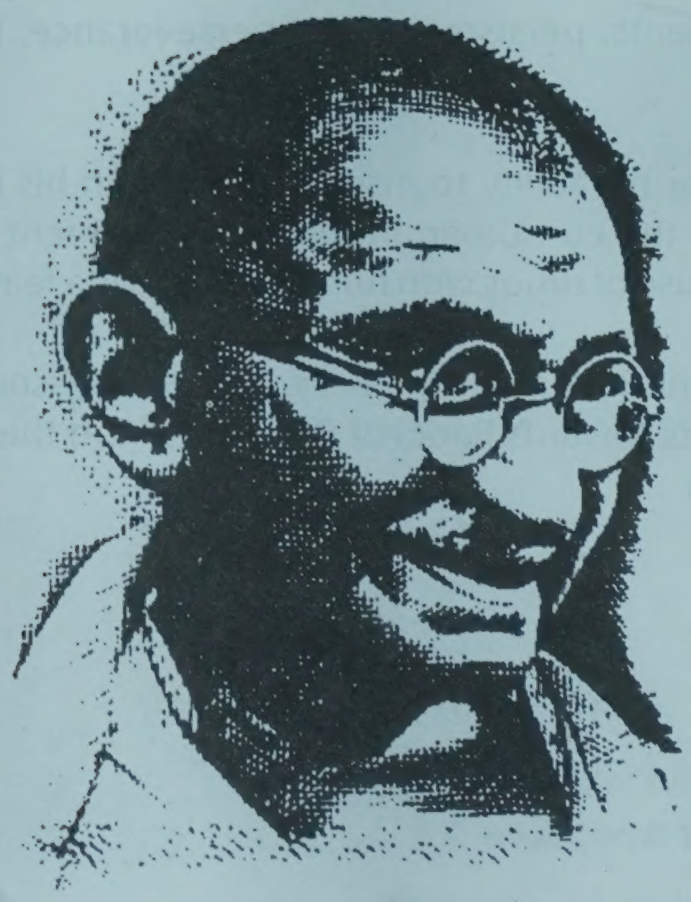
His greatest attribute was his ability to inspire others with his incredible courage. He was the leading light in the consumer and health movement as he fought for truly rational and socially just use of drugs with humility which is a feature of truly great men.

An award has been contributed in his memory. Dr. Olle Hansson award for individuals contributing to the efforts towards Rational Drug Use, from the developing countries.

Remember Gandhi

For those manufacturing medicines and those making policies related to medicines, health and development – where decisions have to be made between profits and people. Remember – Gandhiji's words:

"Recall the face of the poorest and the most helpless man whom you may have seen and ask yourself if the step you contemplate is going to be of any use to him".



Justice Lentin's message for the 4th Edition.

Late Justice B. Lentin (Retd.)
Examiner Press Building
2nd Floor
35, Dalal Street
Mumbai – 400 023

March 6, 1996

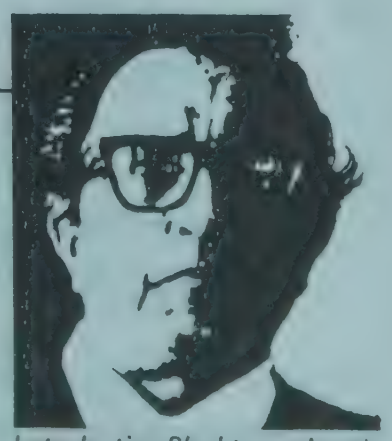
Voluntary Health Association of India is and has been doing commendable work in bringing drugs awareness to the common man, and the live hazards of indiscriminate use of drugs. To this end, present updating of "Banned Bannable Drug List" is a salutary step and in the right direction.

While self-medication is harmful and even dangerous, even more deplorable is the apparent nonchalance of certain medical practitioners in indiscriminately prescribing drugs, and whose prescriptions read like horoscopes.

We have, in this country, far too many drugs and several of them with combinations which are next to worthless. If the present updating can bring awareness not only to the common man but also evoke a positive response from the medical profession, it shall have served its purpose.

Bakhtavar Lentin

Editor's Note -
Justice Lentin contributed very meaningfully to the national efforts in Rational Drug Use through the Lentin Commission Report. He is physically there no more, but he is always remembered with respect and affection.



Late Justice Bhaktavar Lentin

Irrational use of medicines has been described as a new global epidemic by over 450 leading multidisciplinary research workers, national and international policy makers, patient, advocates and clinicians representing nearly 80 countries whc gathered in Chiang Mai, Thailand for the Second International Conference on Improving Use of Medicines (ICIUM), 30th March to 02 April 2004.

They expressed deep concern that almost half the medicines globally are used irrationally. In India the authors of the "Banned and Bannable Drugs" began pioneering work on the issue of irrational use of drugs almost two decades ago. They have now come up with the 5th edition of this very valuable and comprehensive book. It focusses on several important aspects of health and medicines, discussing them in detail and highlights the following:

- Public health dangers due to availability of banned and bannable drugs in the market and their use by unsuspecting consumers.
- The various brand names under which these drugs are marketed in the country.
- Need for consumer information and education. Responding to this need the book provides consumers information on different issues related to health and medicines to ensure that they know their medicines, what they should take and what they should not take and why?
- The need to strengthen regulatory mechanism.
- Prescribers need for unbiased objective drug information through an annually updated comprehensive national drug formulary and therapeutic guidelines.
- The need for international codes to ensure ethical marketing practices by the private drug industry particularly TNCs.
- Public health interests should take precedence over commercial interests in formulating national health and drug policies and international trade agreements.
- Irrational and/or hazardous drug use is not only a danger to public health but also has adverse impact on the economy and leads to economic wastage, as data provided clearly show.

This book is very much more than a list of banned and bannable drugs. It is an advocacy tool for an effective national campaign to demand and call for the formulation, development

and implementation of a Rational Drug Policy based on the Concepts of Essential Drugs and their Rational Use.

The ultimate objective of the book is to ensure regular access to essential drugs at affordable prices to all through the implementation of a rational drug policy.This is one of the important pre-requisites to ensure that the Fundamental Right to Health and Right to Life, becomes a reality in India.

I congratulate the authors for their valuable work and trust that this book will be studied carefully by policy makers, NGOs, health activists, research institutions and academia who will work together to stimulate action which will take India closer to a people and health oriented rational drug policy and rational drug use.

Kind regards,

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Date: 28.6.2004

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The 5th revision of this book like the previous editions has been undertaken by both of us with secretarial support from Mr K.C. Chandrashekhar Nambiar and Ravinder Kumar Sharma and production support from Development Communication Unit of VHAI.

Dr. Mira Shiva
Dr. Wishvas Rane

Contents

HOW TO USE THIS BOOK

This book is divided into two main sections - drugs that are banned by the Indian Government and those which are still allowed but which should be banned or severely restricted, because of their dangers.

- To learn why, and what alternatives are available, turn to the correct page. There you will find details of the dangers, various alternative names for the drug, what it is used for, a list of countries where the drug is already banned or restricted, an example of the contents of one of the brands on the market, and a suggestion for a safer or more rational alternative. Common brands have been printed in capitals for easy reference.

You will also find the names of brands listed as available in the commercial prescribing guides (CIMS AND DRUG TODAY) and in the Indian Pharmaceutical Guides' latest editions. CIMS is used by doctors throughout the country as a source of drug information (in the absence of an unbiased source). Together, CIMS and MIMS influence the prescribing practices of several thousands of medical practitioners.

A large number of drugs not included in CIMS, MIMS and pharmaceuticals index are available in the market. It is hoped that a detailed list inclusive of those drugs will be made available to the public by the drug licensing authorities, as they alone have information pertaining to these brands and manufacturers. It should also be noted that several drugs NOT included in the lists are available in the market. Continued sales of many Banned drugs, post expiry date drugs especially in the periphery where awareness is low.

In some cases the formulation is changed so that recently manufactured products having the same brand name do not contain the hazardous banned or restricted ingredient which was there earlier. It is wise to check the label in case you are sold old (hazardous) stock. Some reformulated brands may have been included in the list, since there is no systematic way of knowing about reformulation. For the same reason, some withdrawn brands may have been retained in the list.

For further information, a list of available material on hazardous, irrational and useless drugs, rational drug use, the banning of drugs, drug policy etc. is provided at the end of the book, together with the source.

A few ideas for further action have been included and aimed at rational drug use for rational health care, to encourage greater awareness, and to stimulate action which will bring us nearer to a people-oriented and rational drug policy and rational drug use.

INTRODUCTION

Many more people are using allopathic western medicines than before. Some medicines are prescribed, some are self-administered and some given by the chemist and druggist to people coming with health complaints.

The nature of healthcare, the public health priorities are increasingly decided by national and international health, economic, trade and industrial policies. The drug corporations and the medical profession have a lot to do with the drug production and drug prescription patterns and the ultimate drug usage.

Not all drugs in the market are rational or essential is a fact known to many but not to a large majority.

There has been deep concern about the large number of drugs flooding the market, of doubtful safety, some with doubtful efficacy, when safer, cheaper and equally effective alternatives exist.

It was the Thalidomide tragedy involving a drug which when given to pregnant women for nausea – morning sickness, resulted in thousands of babies being born in Europe with phocomelia i.e., without limbs. The issue for safety, and patients right to unbiased information was highlighted, and so also the need to .monitor adverse effect of drugs brought into the market. When pregnant women were prescribed Diethyl Stilbaestrol DES to make 'normal babies more normal', daughters born to them on reaching young adulthood presented with vaginal adenoma, which required surgery, and their inability to have normal sexual lives and conceive. It was only after some time that reports of DES sons presenting with infertility because of undescended testis became known, besides the women who took DES themselves presenting with cancer. There are reports of DES granddaughters presenting with vaginal adenoma.

The issue of safety of drugs is not just for the person consuming the drug but also the progeny. **Iatrogenesis** is Drug and Doctor induced problem, and **teratogenesis** is congenital malformation in the unborn foetus caused by drug consumption during pregnancy by the mother.

In absence of Adverse Drug Reaction Monitoring and Post Marketing surveillance, by the pharmaceutical manufacturers of the product – the extent of the problem will never be known. Yet it is very important not just to warn but to ensure that drugs that are potentially hazardous are removed from the market, specially if safer, effective, affordable alternatives exist.

The effort to highlight this concern regarding safety of medicine, right to safe medicines and right to unbiased drug information is over 2 decades old.

The Banned and Bannable Drugs was

brought out initially in cyclostyled form alongwith a lot of other drug education material on hazardous drugs – clioquinols, analgins. This is the 5th edition of Banned and Bannable Drugs attempting to give an update on the drug ban situation. 76 categories have been banned as of May 2004.

It was printed first in 1986 to influence Drug Policy. It was an attempt to highlight the safety aspect of drugs in the market, the need for strengthening the regulatory mechanism, and the need for consumers to be more aware and concerned about issues related to their health, their right to health, their right to essential medicines that were safe, effective and affordable.

This effort towards prevention of use of irrational and hazardous drugs and their withdrawal is part of the broader campaign for **rational drug use** and **rational drug policy**.

The bottomline where consumers are concerned is to encourage them to 'KNOW YOUR MEDICINE', what you should not take and why.

The section on Essential Drugs is to highlight the key concept and principles which guides Rational Drug Policy and Rational Drug Use.

Model list of Essential Medicine 2003 is being included, for use and referral.

Inclusion of the Bangladesh Drug Policy experience, in weeding out irrational and hazardous drugs and the section on Delhi State Drug Policy, is to show that inspite of various constraints positive changes are possible.

We have waited very long and if from need-based cyclostyled lists, a printed book has had to be produced, it has been done for some very specific and important reasons. This book going into the 5th edition has been done as:

- A response to increasing requests and demands from consumer and health groups and individuals for a list of drugs they should not prescribe or consume.
- An effort to focus the attention of the health personnel and consumer beyond brand names to the small print i.e. the content and generic names, the formulation, the reformulation, manufacturer, expiry date, batch number etc.
- An effort to raise public awareness about the need for a Rational Drug Policy in which the question of withdrawal of hazardous and irrational drugs, drug control, drug legislation, adverse drug reaction, unbiased drug information availability have been previously overlooked.
- An effort to ensure that conscientious health personnel and the public insist on representing their views, to safeguard their own health and health of their families by demanding access to safe, quality, essential and life saving drugs.
- An attempt to highlight the need for international codes (besides national

controls and legislation's) where international agencies working for health like WHO should take responsibility to ensure ethical marketing practices of powerful multinationals whose annual turnover is often far beyond the entire national budgets of some developing countries). WHO's Ethical Criteria for marketing of drugs continues to be flouted.

The book is not merely a list of hazardous drugs. It is a tool for demanding action and demanding change. It is clear that no longer can people leave the safeguarding of their health entirely to the policy makers, the drug industry and medical professionals. From this book, consumers can check the contents of a medicine and ensure that they are not unnecessarily taking a hazardous drug. It is an effort to ensure that unbiased drug information is made available to health personnel for responsible prescription writing. Health personnel can demand an annually updated comprehensive National Drug Formulary with therapeutic guidelines, so that availability of such information is ensured.

- India has one of the best-developed pharmaceutical industries of the developing countries, and in spite of over 40,000 formulations in the market, there exist shortages and non-access to essential life saving drugs.
- Continuous flooding in the market of costly, hazardous, and irrational drugs.
- About 20 per cent i.e., one in five drugs tested are substandard and spurious.
- Lack of effective drug control and drug legislation continues.
- Non-availability of unbiased drug information.
- Increasing drug prices.
- Increasing privatization of drug dispensing and drug prescribing with a move towards fee for service from Govt. health infrastructure.

All these are totally unacceptable in a democracy. We are a country with the world's third largest medical manpower. We are signatory to the Alma Ata Charter of 1978 and we had issued a very progressive sounding National Health Policy statement in 1983 which was not implemented, followed by National Health Policy of 2003 with clear moving away from 1983 policy direction. We are acknowledged as a Third World leader and we say India is shining. It is definitely shining for a privileged minority. Yet it is here where about 1/3 of our people live below the poverty line, that half of the world's TB patients, one third of the world's leprosy patients struggle to survive. Here 1/3rd of the newborn babies are born of low birth weight, children still die of preventable and easily treatable diarrhoeas.

The impact of Structural Adjustment programmes on social sectors like health have been significant, as IMF insisted on cuts in Fiscal Deficit. This is reflected in the systematic decrease in the expenditure on health and education. World Bank policies

towards privatization and verticalisation were a move away from comprehensive approach.

Resurgence of epidemics of Plague in 1994, Falciparum Malaria in 1994 in Rajasthan, in 1995 in Assam, in 1996 in Mewat with Dengue Harmorrhagic Fever (DHF) in Delhi in 1996 is a matter of concern and so also is the unparalleled spiraling of drug prices and medical care costs.

Medical expenditure by those who are most vulnerable to ill health and who have little purchasing power, has resulted in increasing burden of personal loans for medical treatment, and this has emerged as a major cause of rural indebtedness.

Emergence of drug resistance with communicable diseases, resistance to pesticides and spread of vector borne diseases specially Falciparum Malaria, Kala Azar, TB and Japanese B Encephalitis has resulted in serious concerns for the future.

Drug Policy was formulated in 1986, ironically as "rationalization measure for the growth of the Drug Industry", and then in 1994 in keeping with the new Industrial Policy and a shift towards decontrol, liberalization, deregulation. Health, consumer and women's group maintain that there should be no liberalization without rationalization. Liberalization, privatization, globalization processes have never served the poor majority.

In the International Classification of disease, a new category Z59.5 was added. Z59.5 stands for "extreme poverty", which the World Health Report of 1995 "Bridging the Gap" says is increasing, between countries and within countries. What we are seeing is the increase in inequities in every sphere including health.

The Pharmaceutical Policy 2002 was further removed from public health.

The Banned Bannable Drug List is a reminder about the need to look at medicines from a 'public health' and not just a 'trade' perspective. BBDL is a tool for health awareness and health action. Aggressive marketing is one thing but exploitation in the name of medicine is something else, by denial of information about safety. Recognizing this as an area of public concern the National Human Rights Commission has formed an expert group on safety of medicines and medical devices.

The Mashelkar Committee report on comprehensive examination of drug regulatory issues including the problem of spurious drugs has been tabled in the parliament in November 2003, and one of the objectives is to ensure follow up.

Medicines as they deal with life and death, with pain and suffering cannot be treated as a mere profitable trade and commodity like cosmetics. They have a role in health care, limited though it may be. Commercialization and pharmaceuticalization of health care has to be resisted. As ensuring presence of all these factors that go in determining health are ensured, socially conscious health personnel and public can help create a

sensible market demand. High health literacy and awareness, knowing your medicine, refusing to prescribe and consume hazardous and irrational drugs is the first step in this effort.

With the increasing commercialization of healthcare, its increasing cost and dependency on costly technologies, it is extremely critical to differentiate between essential, rational, life saving drugs and medical technologies vs profit-oriented, non-essential, irrational and hazardous drugs and medical technologies.

In mid 80s, led by Dr. Olle Hansson, over 3,000 doctors in Sweden, Denmark, Finland and Norway boycotted Ciba-Geigy products for its continued sales of Mexaform and Enterovioform in the Third World (See the Clioquinol Section for details). The boycott resulted in a fall in the drug sales of Ciba-Geigy products, linked with economic losses and therefore withdrawal of the product.

Several health and consumer groups who feel strongly about these issues have been actively involved in drug and health education and in promoting health action to meet contemporary health challenges. Voluntary Health Association of India (VHAI), the All India Drug Action Network (AIDAN) , Delhi Society for Promotion of Rational use of Drugs, Action for Rational Drugs in Asia (ARDA), Health Action International (HAI) and MSF are examples of such coordinated health action. Responding to their social responsibility, physicians, health personnel protested against use of nuclear energy for destruction, against war, against militarization, and against unjust international Trade Regimes. This merely indicates that today there is a crying need for socially responsible action of professionals and consumers alike, to ensure access to essential drugs, that are of quality, affordable and safe; and resistance against hazardous products and technologies, which are posing an emerging public health problem.

As disparities are growing between the countries of North and South, and also within the countries where a super privileged class has access to world class medical care, and ecologically destructive, lifestyles devoid of sense of humanity, where caring, compassion is seen as unprofitable, unpragmatic, inefficient and a weakness; and self indulgence and self aggrandizement as success, while a majority struggle to survive, facing worsening economic, social and political insecurity. Such a life philosophy results in increasing marginalisation of the vulnerable, the old, the disabled, the women and children. The physical, mental, social, ecological burden and disease burden of the marginalised is the worst. Hence the issue of **right to essential medicines, right to safe medicines is closely tied with the right to health, right to livelihood of dignity and right to life.** The issue is not of access to medicines alone.

Pressure to change the model Indian Patent Act of 1970 in keeping with TRIPS agreement of World Trade Organisation (WTO) will have its own implications in

terms of increased costs and decreased access and affordability. A concern expressed by WHO as well as international health organizations e.g., HAI, MSF, OXFAM, TWN, IPHC and PHM.

The growth of the unregulated market and the market concerns guiding policy making has tended to weaken civil society initiatives based on social justice, promoting partnerships that promote techno managerial approaches to health care, within a biomedical reductionist, western medical model framework with vertical approach. Using financial, social, psychological insecurity as a means of control. Increasing corporate power and market influence with profit orientation has eroded consumer concerns as well as rights of workers.

There are few priority areas in public health where there is a need for concerted action by people, to actively influence and bring about change as in the drugs issue. Once doctors refuse to prescribe and people refuse to take hazardous, irrational and non-essential medicines and medical technologies prescribed or otherwise, change is entirely in their own hands. Refusal to take such pill is political action, said Ivan Illich. It is consumer action.

Efforts towards humanized healthcare, humanized living and humanized ecological sustainable development are interconnected. Refusal to accept pills and policies destructive to humankind is part of the same effort, and a part of the same process.

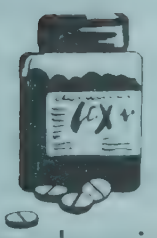
This peaceful resistance against hazardous and irrational drugs and exploitative healthcare is essential in the self-interest of individuals and in the interest of society. Consumer groups call it "Boycott: Gandhi, called it "Satyagraha". A call for "Rational Drug Use" is a reflection of that spirit and is a call for action.

The drug policies formulated so far have failed to safeguard public interest. Hathi Committee was appointed in 1974 to undertake a thorough analysis of the Indian drug industry. The Hathi Committee made some important observations and recommendations such as:
IT ATTEMPTED FOR THE FIRST TIME A FORMULATION OF AN ESSENTIAL DRUG LIST, not that the drug policies followed up with an Essential Drug Policy, whereby production, distribution and prescription patterns were influenced by it. It was formulated in 1996 and updated as National List of Essential Medicines in 2003.

Hathi Committee recommended a package of price control measures to make life saving and essential drugs affordable. (DPCO 1979, started with a categories of drugs with price controls ranging from 40 per cent to 55, 75 and 100 per cent and the open category of non-essential and simple remedies with unlimited profits. Drug Price Control Order (DPCO) 1987 raised the profit margin of category I drug to 75 per cent and Category II to 100%, decontrolling the rest. DPCO 1995 abolished the different categories and the category I & II are brought under a single common list with uniform MAPE of 100 per cent and the rest

of the drugs being price decontrolled.

The price control basket has systematically shrunk with each DPCO.



- from 343 drugs in 1979
- to 142 drugs in 1986
- to 76 drugs in 1995
- 26 drugs in 2003 (as was planned earlier but is being reviewed by the chemicals ministry)

NONE OF THESE MEASURES HAVE MADE ESSENTIAL LIFE SAVING DRUGS ADEQUATELY AVAILABLE AT AFFORDABLE PRICES, BUT THE NON-ESSENTIALS HAVE PROLIFERATED, AS IS OBVIOUS FROM TABLE.

Top Selling Brands in India as per ORG-Nielsen Retail Audit, October 2003

Sl.No	*Brand Name*	*Uses and Remarks*	*Moving annual turnover in rupees crores (retail sales)*
1.	Corex	Cough suppressant. Abused as drug of addiction because of presence of codeine	88.18
2.	Neurobion	Irrational Multivitamin preparation	60.27
3.	Revital	Completely irrational preparation with ginseng and multivitamins	47.64
4.	Phensedyl	Cough suppressant	47.30
5.	Glucon-D	Glucose preparation with no therapeutic value	42.79

Source: Figures from ORG-Nielsen Retail Audit, October 2003 as quoted in MFC Bulletin, 2004.

Top Selling 10 Categories of Drugs in the Top 300 Brands: Where is the People's Money Going?

Type of drug category	*No. of Brands*	*Moving annual total (in crores of rupees)*	*Remarks*
1. Anti-infectives	65	1650.02	Most frequently used and abused drugs when antibiotics are given for fever due to viral infections

2. Analgesics	26	705.06	Hazardous analgesics like Nimesulide are one of the top sellers
3. Endocrine disorders like diabetes mellitus, hormones	25	694.10	
4. Multivitamins and minerals	27	651.29	Contains predominantly non-essential drugs in all kinds of irrational combination
5. Drugs for cardiovascular disease	26	601.64	The top selling cardiovascular drug is one that has little therapeutic advantage over less costly alternatives
6. Drugs for respiratory system, including cough preparations	21	512.59	Cough syrups sell more than drugs for asthma
7. Drugs for gastrointestinal system	20	427.21	Their large scale is also the result of over prescription
8. Drugs for allergy	10	326.51	
9. Anticonvulsants	9	221.35	
10. Hematinics	6	128.13	Contains such irrational wonders of the pharmaceutical world as Dexorange (57 crores) which till recently contained animal blood from slaughter houses, hepatoglobin, etc.

Source: Figures from ORG-Nielsen Retain Audit, October 2003 as quoted in MFC Bulletin, 2004.

Hathi Committee recommended a gradual shift to GENERIC names from brand names. The shift to generic names was blocked by Hoechst, Cyanamid and Pfizer by obtaining stay orders from Delhi High Court in 1981 and the case continues to languish in Supreme Court and a final judgement was awaited as of May 1995. Though brand generic prescribing is required in the labeling, the mindset is still Brand oriented though the banning of drugs continues under generic names expecting doctors and public to find out on their own.

The drugs banned so far are 76 categories. The ban orders are in general names. An effort to provide the related brand names of the various categories.

The brand names are taken from MIMS, CIMS, Drug Today and Indian Pharmaceutical Guide. There is a possibility that a few of these brand name products may not be available, but because the brand names are included in the reference guides, the same are mentioned. There is also a possibility that since the enforcement of government ban order, a few of the manufacturers may have reformulated but kept the same brand names. We shall be obliged if the readers inform us of such changes or discrepancies to enable us to effect the corrections in the subsequent editions. In some cases the brand names are purposefully given in a misleading way. For example Phensedyl contained promethazine (anthithistamine) with codeine and ephedrine. Combination of ephedrine with antithistaminic is banned as a cough mixture. So they do not call this as a cough remedy. Instead they have another preparation with a brand name 'Phensedyl expectorant' which contains only anthihistamine with guaicol and menthol.

Of the 80 top selling products, 23 (nearly 30 per cent) are either irrational, or hazardous or both. The combined sale of these 23 drugs was Rs. 286.63 crores, i.e. almost 10 per cent of the total sales in 1992. This clearly shows that the earlier two DPCO's (1979 and 1987) have helped in the growth of irrational drug combinations. The new DPCO 1995 has further reduced the number of products under price control and it will further increase the irrational and non-essential drugs and drug combinations. In these circumstances a book like Banned and Bannable Drugs: Unbiased Drug Information, Essential Drugs & Rational Drug Policy gains more importance.

With rapid development in Science and Technology there has been an explosion in the number of drugs which are available in the market. US FDA has reported that of the 348 new drugs from US drug companies only a very small percentage made a modest potential contribution, and 84 per cent made little or no potential contribution. A French study of 508 new Chemical entities marketed in the world between 1975 and 1984 found 70 per cent offered no therapeutic improvement over existing products. The situation in India is no different and will probably worsen over a few more years of liberalization and decontrol. Between 1975 and 1996, 1223 new chemical entities were developed –

only 11 of these were for treating tropical diseases. Last major new anti TB drug was 30 years ago, drugs for diseases of poverty are not developed because of lack of market and profits.

There are an estimated 20-30 thousand brands of various drugs available in the Indian market. In such a situation and particularly where majority of the drugs are fixed dose combinations, with health being a state subject, the task of an already over-stretched Drug Control Authority becomes almost impossible to cope with.

The 14 deaths of innocent ophthalmic patients due to use of industrial rather than 'medicinal' glycerol in J.J. Hospital, Mumbai (referred to in detail in Lentin Commission Report) and 7 deaths to 'life saving' I.V. Fluid in Delhi shows the state of quality control in India. How can the quality of hazardous or irrational drugs be assured? Such drugs must be withdrawn, so as not to overload the already inadequate drug control machinery. Availability must be ensured of low cost and good quality of essential life saving drugs.

When a tribal dies of Malaria because of non-availability of 12 tablets of chloroquin, a drug of yesteryears, any talk of R&D for drugs for enhanced potency, weight loss, antiaging sound so hollow. The R&D priorities are for drugs meant for the privileged and those with the purchasing power. Drug needs for the poor majority in developing countries are not a priority. The initiative taken by MSF for promoting R&D on drugs for neglected diseases (DND) is a laudable effort. Threat of putting countries on watch list under Special 301 by US and arm twisting under bilateral and multilateral pressure under TRIPS will make availability of essential life saving drugs still under patents more difficult. To our minds this is a public health violence.

The question is no longer just of economic wastage. In a country with around 26% of the population below or around the poverty line, it is a matter of serious life and death concern, and exploitation in the name of medicine. The issue of medicines is a major public health problem and must be addressed as such. In the absence of monitoring of adverse drug reactions i.e. the side effects of medicines, and majority of the cases of iatrogenesis i.e. "doctor induced problems" continue to be missed. It is only tragedies such as Thalidomide Tragedy, DES and Halcion Tragedy, the J.J. hospital glycerol deaths and deaths due to contaminated I.V. fluids that focus public attention on the problems related to unsafe medicine.

A Public Interest Litigation 693/1993 had been filed in the Supreme Court in 1993 to screen and weed out irrational and hazardous drugs by All India Drug Action Network, Drug Action Forum, Karnataka, NCCDP and other Voluntary Health Organizations e.g., Locost, CDMU etc. Several irrational therapeutic categories of drugs have since been banned and others have been theoretically restricted. These banned drugs have been included in this 5th edition.

Revision of the "Banned and Bannable

Drugs" is VHAI's contribution to the ongoing effort towards Rational Drug Use and Rational Drug Policy.

This book is an effort in people's advocacy and people's education for Health Action. If access to drugs of yesterday cannot be ensured for neglected diseases etc., Kala Azar, TB, Malaria to expect any equity in an increasingly intolerant, inequitable world in the future will not be realistic. For ensuring of availability of anti-retroviral drugs, the pressure by anti-AIDS and health activists in South Africa, at the World Health Assembly, during elections in US, at inter-ministerial meetings in Doha and Cancun made a difference, with a responsible response from WHO. Ninety per cent decrease in the prices of anti-retroviral drugs for HIV/AIDS did not take place on its own. For millions, this means 'hope' and possibility to live a few years more. The Special Leave petition (Civil) No.423 of 2003 petition under Article 32 of Constitution of India filed by AIDAN, MFC, LOCOST and JSS on Essential Drugs and Drug Pricing is part of the same effort, to ensure access to essential drugs, at affordable prices as people have 'Right to health' and 'Right to life'. This book is an effort to uphold that right.

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3 Consumer Action

WHAT YOU CAN DO

Know Your Medicines, Know About Problem Drugs

1. Stop using banned and hazardous drugs.

2. Stop using useless and irrational drugs.

3. Tell your family, friends, neighbours and community about banned,bannable, hazardous and useless drugs.Inform them of safer and better alternatives. Always ask for a cash memoand keep it safely, which is necessary forany possible consumer action.

4. Inform local doctors, chemists and health workers about the banned drugs.

5. Avoid combination drugs. Buy single ingredient drugs as far as possible.

6. Avoid unnecessary, expensive brand-named drugs, ask for the prescription, buy the generic equivalents, but of equivalent reliable companies. ALL DRUGS IN THE MARKET SHOULD BE QUALITY DRUGS, BRAND OR GENERICS

7. Refuse to take a drug if its expiry date is over, or if it is discoloured and if there are suspended particles in it. LOOK AT THE EXPIRY DATE before purchasing drugs.

8. Report shortages of essential and life saving drugs, specially those required for the National Health Programme e.g., home based fluids in diarrhoea, how to decontaminate water with chlorine to your State Health Secretary, Director General Health Services and the State FDA, VHAI and AIDAN (addresses are given at the back of the book). Acquire health literacy.

9. For common simple problems, encourage the use of traditional home remedies, instead of expensive and unnecessary drugs for trivial problems and k n o w when to seek medical help e.g., increase in respiratory rate in children suffering from common cold, as this could be a sign of pneumonia.

10. Encourage and demand preventive health measures like potable drinking water supply, sanitation, enough nutritious food, appropriate immunization, essential health services, healthy environment and safe working conditions so that diseases do not occur in the first place.

11. Whenever you are prescribed a drug, ask your doctor politely how to take it, how often, what side-effects may occur, how long you

should continue taking the drug, what are the expected benefits, and whether there would be any other problem with other drugs being taken and whether you should avoid certain food or drink while taking the drug. Obtain and encourage other people to obtain this important information from their doctors especially in the case of pregnancy, liver or kidney damage, or known drug sensitivity, a s k about availability of cheaper, equally effective alternatives. Know your rights as a patient.

12. Support health, drug action, consumer, social action and other groups which are striving for rationaldrug use and justice in health care.

13. Monitor the inclusion or absence of package inserts (printed information with drug packs). Theseare important specially for newer drugs.

14. If given a very long prescription, find out which are the most essential drugs for your health problems and which drugs can be avoided e.g., costly tonics that could be substituted by food. This can be ascertained from your doctor (Studies have shown that many patients due to resource crunch can buy the drugs only for one day and that they buy only the first one or two drugs listed on long prescription drugs which may not be the most essential. (Doctors are encouraged to write the most essential drugs first in their prescription).

15. Ensure that anyone prescribed antibiotics or put on long-term treatment, as for TB or leprosy, takes his/her medicine regularly and for proper length of time to avoid emergence of drug resistance.

16. For basic information on use of drugs refer to "Where There is No Doctor" David Werner (adapted by and available with VHAI). The green pages deal specifically with drugs and their dosages, their indications, precautions, etc. Others are Lay Person's Guide to Medicine, LOCOST, Family Medicine Book, Dr. Bapna etc.

17. Form a Local Health Committee and supervise availability and utilization of the drugs in government health institutions etc. Primary health centres and dispensaries or encourage the existing committees to do so.

18. Report side effects if any, to your doctor and in case of serious fatal side effect also inform ICMR.

For Health Personnel

19. Educate your community about hazardous and useless drugs, and alternative remedies, using posters, puppet shows, street theatre, slideshows, public meetings, articles and letters in the local newspapers, publications in local languages, etc.

20. Form an action committee of concerned groups and individuals to create awareness of the situation, and bring about change. Link up with VHAI, All India Drug Action Network and its members and consumer organisations.

21. Encourage your local health workers to recommend drugs only when necessary to suggest appropriate known well tried simple home remedies for trivial complaints with appropriate referral when needed.

22. Encourage your local doctors to prescribe only essential and appropriate single ingredient drugs (despite pressure to do otherwise from both the patients and the drug salesmen).

23. To help facilitate monitoring of continued sales of banned drugs, you can buy banned drugs, obtain a cash memo and send copies to your State Drug Controller, the Drug Controller of India and VHAI.

24. Introduce your local doctors and health workers to sources of unbiased, up-to-date drug information so they are not solely reliant on drug companies' sales literature and commercial prescribing guides.

25. Report to your State Drug Controller, the Drug Controller General of India and VHAI any incentive schemes, or free gifts offered to doctors in return for buying or prescribing certain drugs.

26. Conduct a drug utilization study in your area. Find out how drugs are being misused or overused, how much people are spending on useless drugs, whether they are using hazardous drugs, whether health workers have up-to-date drug information from unbiased sources, how many drugs are sold over-the-counter or by prescription only. Publicize the results and work to improve the situation.

27. Study the commercial prescribingcost, content and easy availability of oral rehydration packet. (E.g. MIMS and CIMS, Drug Today), salesliterature of the drug companies and the labels/package insert of drugs. Compare this information withstandard textbooks. Look particularly at the contraindications (conditions when the patient should not take the drug) and warnings of side effects. Inform the publishers of the commercial guides, drug companies concerned, Drug Controller, AIDAN and VHAI of any significant differences you find between the commercial information and that contained in the textbooks.

28. Study the contents of popular brands of over-the-counter painkillers etc. Discover whether they contain any hazardous drugs and whether the active ingredients a r e

included in sufficient amounts to be useful. Compare the price. Publicize your results.

29. Compare the increase in present year's from previous year's drug prices and availability of essential and life saving drugs, especially drugs for National Health Programmes.

30. Support any initiatives to preserve, document or improve traditional local health care system, which can increase self-reliance.

31. Educate your community about the irrationality and high-cost of tonics. Show how much good food one can buy for the price of a bottle of tonic.

32. Organize a local Oral Rehydration Campaign, so that every household knows the best treatment for diarrhoea and how to prepare it from household ingredients and where to access, UNICEF/WHO ORS packets, and chlorine tablets for decontaminating water. Warn people of the dangers and uselessness of most anti-diarrhoeal drugs, and the dangers of not giving oral rehydration, especially to young children in early diarrhoea.

Find out about the Adverse Drug Reaction of the drugs that you prescribe specially drugs used in PREGNANCY for Teratogenic effects of drugs. (See Chapter 20).

33. Report Adverse Drug Reactions encountered by you in your practice to ADR monitoring centres and since there is a gross lack of ADR centres, raise it as a legitimate public health demand.

Note: There is a WHO Ethical Criteria for marketing of drugs and an International Pharmaceutical Manufacturers Association Code of Conduct in drug marketing. Inform them and us of violations.

UNETHICAL MARKETING PRACTICES AND DOUBLE STANDARDS

The market for non-essential irrational and even hazardous drugs will continue to grow till there are policies that protect the consumers, or consumers that protect themselves. One of the most important tool for rational consumption of drugs is access to unbiased drug information and ensured availability of only safe and rational products.

Not merely are Brands promoted with suppressions of the negative facts but half-truths are told to misguide prescribers and consumers.

In the past, reference of Lancet has been used in the promotional package by Glaxo to promote Osteocalcium B-12 when it was not even referred there. This was an example of provision of biased drug information. Boehringer Knoll had misused UNICEF logo to promote chloramphenical streptomycin combination, streptoparaxin as an anti-diarrheal, which has since been removed. Both these were presented in the International Consultation of Experts on

Rational Drug Use in Nairobi in 1985.

The ethical guidelines for marketing were formulated, facilitated by WHO. Ethical guidelines as every one knows are not legally binding.

Changes of indications on paper, to escape the drug bans even when they do come too late and too ineffectual - takes care of the legal aspects, without really affecting the sales and the market negatively, for the manufacturers and distributors.

Several products sold in India were not allowed to be sold in the parent country. Netherland's Organon (Infar's) High dose Estrogen progesterone combination MENSTROGEN was a perfect example.

Analgin combinations were not allowed in Germany, Hoechst's parent country but were sold in India.

Restricted use of Drugs is only possible if both public and private medical services feel bound to decrease the use of non-essential irrational and even hazardous drugs.

Further non-formulation and non-implementation of an Essential Drug Policy and an Essential drug list results in more and more usage of irrational and non-essential drugs by health institutions, health personnel and consumers.

4 List of Banned Drugs

CATEGORIES WITH GSR NUMBER AND DATE OF BANNING

COMPARISON OF PREVIOUS RECOMMENDATIONS WITH THE GAZETTE NOTIFICATION OF JULY 1983 AND GAZETTE NOTIFICATION SINCE THEN TILL APRIL 2004

You can compare the drugs which were recommended for banning by experts, with the drugs which were actually banned, by following the lists horizontally from left (the first recommendations) to right (the ban order). Many of the recommendations were not followed for long. The number in brackets indicates order in the original document.

Recommended by sub-committee of Drug Consultative Committee 1980	**Drug Technical Advisory Board Report 25 May 1982**	**Gazette Notification of Drug Controller of India July 23, 1983 No. X 1014/1/83**
To be weeded out immediately		Banning, manufacture, import or sale
1. Fixed dose combination of steroids.	(15) Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for treatment of asthma	(14)[1]Fixeddose combinations of cortico steroidswith any other drug forinternal use. GSR No.105T(E) 3-11-1988
2. Fixed dose combinations of amidopyrine	(1) Fixed Dose combinations of amidopyrine	(1) Amidopyrine GSR No. 578(E) 23-7 1983
3 Fixed dose combinations of chloramphenicol	(16) Fixed dose combinations of chloramphenicolexcept preparation of chloramphenicol and streptomycin.	(15)[2] Fixed dose combinations of chloramphenicol with any other drug for internal use. GSR No.105T(E) 3-11-1988
4. Fixed dose combinations of ergot	(17) Fixed dose combinations of ergot except combinations of its alkaloid ergotamine with caffeine.	(16) Fixed dose combinations of ergot. Ergot preparation except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine headache. GSR No. 304(E) 7-6-1991
5. Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers.	(2) Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers	(2)Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers. GSR No. 578(E) 23-7-1983

1. Fixed dose combinations of cortico steroids with any others drugs for internal use was banned in 1988.
2. Fixed dose combination of chloramphenicol with any other drugs for internal use was banned in 1988.

6. Fixed dose combinations of atropine in analgesics and anti-pyretics.	(3) Fixed dose combinations of atropine in analgesics and anti-pyretics.	(3)Fixed dose combinations of atropine in analgesics and anti-pyretics. GSR No. 578(E)
7. Fixed dose combinations of analgin	(Excluded)	(Excluded)
8. Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins	(5) Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins	(5) Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins. GSR No. 578(E)
9. Fixed dose combinations of iron with strychnine, arsenic and yohimbine.	(6) Fixed dose combinations of iron with Strychnine, Arsenic and Yohimbine.	(6) Fixed dose combinations of iron with Strychnine, Arsenic and Yohimbine. GSR No. 578(E)
10. Fixed dose combinations of sodium bromide/ chloralhydrate with other drugs	(7) Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.	(7) Fixed dose combinations of sodium bromide/chloral hydrate with other drugs. GSR No. 578(E) 23-7-1983
11. Fixed dose combinations of tetracycline, analgin with vitamin C	(13) Fixed dose combinations of tetracycline with vitamin C	(12) Fixed dose combinations of tetracycline with vitamin C GSR No. 578(E) 23-7-1983
12. Fixed dose combinations Ayurvedic drugs with modern drugs	(8) Fixed dose combinations of Ayurvedic and Unani drugs with modern drugs.	(excluded)
13. Fixed dose combinations of phenacetin	(9) Fixed dose combinations of phenacetin.	(8) Phenacetin. GSR No. 578(E) 23-7-1983
14. Fixed dose combinations of chloramphenicolwith streptomycin	(excluded)	(excluded)
15. Fixed dose combinations of penicillin with streptomycin. 16. Fixed dose combinations of more than one anti-histaminic.	(excluded)	(excluded) GSR No. 93(E) 25-2-1997
16. Fixed dose combinations of more than one anti-histaminic.	(excluded)	(excluded)

To be weeded out over specific time:

1. Fixed dose combinations of anti-histaminics in anti-diarrhoeals.	(10) Fixed dose combinations of anti-histaminics with anti-diarrhoeals.	(9) Fixed dose combinations of anti-histaminics with anti-diarrhoeals. GSR No. 578(E) 23-7-1983

2. Fixed dose combinations of penicillin with sulphonamides	(11) Fixed dose combinations of anti-histaminics with anti-diarrhoeals.	(10) Fixed dose combinations of pencillin with sulphonamides. GSR No. 578(E) 23-7-1983
3. Fixed dose combinations anti-histaminics with tranquilizers.	(excluded)	(excluded)
4. Fixed dose combinations of tranquilizers, anti-histaminics and analgesics.	(excluded)	(excluded)
5. Fixed dose combinations of vitamins with analgesics.	(12) Fixed dose combinations of vitamins with analgesics.	(11) Fixed dose combinations of vitamins with analgesics. GSR No. 578(E) 23-7-1983
6.Fixed dose combinations of paracetamol with anti-histaminics and iranguilizers.	(excluded)	(excluded)
7.Fixed dose combinations of prophylactic vitamins in anti TB drugs except INH with vitamin B6	(18) Fixed dose combinations of prophylactic vitamins with anti-TB drugs except combination of INH with vitamin B6	(17) Fixed dose combinations of vitamins with anti-TB drugs except combination of Isoniazide with Pyridoxine Hydrochloride (vitamin B6) GSR No. 304(E) 7-6-1991
Additions of DCC List	(4) Fixed dose combinations of strychnine and caffeine in tonics.	(4) Fixed dosed combinations of strychnine and caffeine in tonics. GSR No. 578(E)
	(14) Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery.	(13) Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery and for external use only. GSR No. 793(E) 13-12-1995
Additions to DTAB list		(18) Penicillin skin/eye ointment GSR No. 304(E) 7-6-1991 (19) Tetracycline liquid oral preparations GSR No. 304(E) 7-6-1991 (20) Nialamide GSR No. 304(E) 7-6-1991 (21)Practolol GSR No. 304(E) 7-6-1991 (22) Methapyrilene, its salts GSR No. 304(E) 7-6-1991

Addition of Gazette Notification 1984		(23) Methaqualone GSR No. 49(E) 31-01-1984 (24) Oxytetracyline liquid oral preparations GSR No. 322(E) 3-5-1984 (25) Demeclocycline liquid oral preparations. GSR No. 322(E) 3-5-1984
Addition to Gazette Notification 1985		(26) Combination of anabolic steroids with other drugs. GSR No. 863(E) 22-11-1985 (27) High dose Oestrogen and Progestin combinations. Fixed dose combination of Oestrogen and Progestin (Other than oral contraceptives) containing per tablet Estrogen content of more than 50mcg (equivalent to Ethinyl Estradiol) and Progestin Content of more than 3mg (equivalent to Norethisterone Acetate) preparations and fixed dose combination injectable preparations containing synthetic Oestrogen and Progesterone. (Subs. No.743(E) 10-8-1989) GSR No. 863(E) dt. 22-11-1985
Addition to Gazette Notification 1988		*(14)[1] Fixed Dose Combination of Corticosteroids with any other drug for internal use. *(15)[2] Fixed Dose Combination of Chloramphenicol with any other drug for internal use.
Additions to Gazette Notification 1990	Issued on: 26.12.90 Issued by: Balbir Singh, Joint Secretary	**Gazettee Notification of Drug Controller of India No. X 11014/ 3/88. DMS & PFA** 28 Fixed dose combinations of Sedatives/hypnotics/anxiolytics with analgesic antipyretics. GSR No. 999(E) 26-12-1990 29 Fixed dose combination of Pyrazinamide with other anti-tubercular drugs except combination of Pyrazinamide with Rifampicin and INH as per recommended daily dose given

		below: *Drugs* *Minimum* *Maximum* Refampicin 450mg 600mg INH 300mg 400mg Pyrazinamide 1000mg 1500mg GSR No. 999(E) 26-12-1990

In July 1993 Fixed dose combinations of Steroids for internal use except combinations of steroids with other drugs for treatment of asthma were banned.
Similarly fixed dose combinations of Chloramphenicol for internal use except combinations of chloramphenicol and streptomycin were banned.

		30. Fixed dose combination of histamine H2-receptor antagonists with antacids except for those combinations approved by the Drugs Controller, India. GSR No. 999(E) 26-12-1990 31. The patent and proprietary medicines of fixed dose combinations of essential oils with alcohol having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia. GSR No. 999(E) 26-12-1990 32. All Pharmaceutical preparations containing Chloroform exceeding 0.5% w/w or v/v whichever is appropriate. GSR No. 999(E) 26-12-1990
Additions to Gazette Notification 1991	**Issued on : 11.2.91** **Issued by : Balbir Singh, Joint Secretary**	**Gazette Notification of Drug Controller of India No. X 11014/ 4/90. DMS & PFA** 33. Fixed dose combination of Ethambutol with INH other than the following : INH Ethambutol 200mg 600mg 300mg 800 mg GSR No. 69(E) 11-02-1991 34. Fixed dose combination containing more than one antihistamine. GSR No. 69(E) 11-02-1991 35. Fixed Dose combination of

		anthelmintic with cathartic/ purgative except for piperazine. GSR No. 69(E) 11-02-1991 36. Fixed dose combination of Salbutamol or any other bronchodilator with centrally acting anti-tussive and/or antihistamine. GSR No. 69(E) 11-02-1991 37. Fixed dose combination of laxatives and/or anti-spasmodic drugs in enzyme preparations. GSR No. 69(E) 11-02-1991 38. Fixed dose combination of Metoclopramide with other drugs except for preparations containing metoclopramide and aspirin/paracetamol GSR No. 69(E) 11-02-1991 39. Fixed dose combination of centrally acting anti-tussive with antihistamine having high atropine like activity in expectorants. GSR No. 395(E) 19-5-1999 40. Preparations claiming to combat cough associated with asthma containing centrally acting anti-tussive and/or an antihistamine. GSR No. 395(E) 19-5-1999 41. Liquid oral tonic preparations containing glycero-phosphates and/or other phosphates and/or central nervous system stimulant and such preparations containing alcohol more than 20% proof. GSR No. 395(E) 19-5-1999 42. Fixed dose combination containing pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed. GSR No. 395(E) 19-5-1999
Additions to Gazette Notification 1992	**Issued on 30.4.92 Issued by B.S. Lamba, Jt Secretary**	**Gazette Notification of Drug Controller of India No. X11014/ 3/91. DMS & PFA**

		43. Chloral Hydrate as drug GSR No. 304(E) 07-06-1991 44*Toothpaste/Toothpowder containing Tobacco 45. Dovers Powder Tablets 1P GSR No. 612(E) 09-08-1994

44* In addition to the above-mentioned drugs, manufacture and sale of all Cosmetics and all Ayurvedic drugs licensed as toothpaste, tooth powders containing tobacco have been prohibited under G.S.R 443 (E) dated 30.04.1992.

Additions to Gazette Notification 1994	**Issued on 30.9.94 Issued by Shailja Chandra, Jt Secretary.**	Gazette Notification of Drug Controller of India No. X11014//490. DMS & PFA. **Sept. 30, 1994.** 46. Antidiarrhoeal formulations containing Kaolin or Pectin or Attapulgite or activated charcoal. GSR No. 731(E) 30-09-1994 47. Antidiarrhoeal formulations containing Phthalyl Sulphathiazole or Sulphaguanidine or Succinyl Sulphathiazole. GSR No.731(E) 30-09-1994 48. Antidiarrhoeal formulations containing Neomycin or Streptomycin or Dihydrostreptomycin including their respective salts or esters. GSR No.731(E) 30-09-1994 49. Liquid Oral antidiarrhoeals or any other dosage form for pediatric use containing Diphenoxylate or Belladonna including their salts or esters or metabolites hyosymine or their extracts or their alkaloids. GSR No. 731(E) 30-09-1994 50. Liquid oral antidiarrhoeals or any other dosage form for paediatric use containing halogenated hydroxyquinolines. GSR No. 731(E) 30-09-1994 51. Fixed dose combination of antidiarrhoeals with electrolytes. GSR No. 731(E) 30-09-1994
Additions to Gazette Notification 1995	**Issued on 7.2.95 Issued by Shailja Chandra, Jt Secretary.**	**Gazette Notification of Drug Controller of India, Feb. 7, 1995 No. X11014//8/94. DMS & PFA.**

		52. Patent and Proprietary Oral Rehydration salts other than those conforming to the following: a) Patent and Proprietary Oral Rehydration Salts on reconstitution to one litre shall contain: sodium 50-90 millimoles. Total osmolarity – 240-290 milliosmoles, Dextrose: Sodium molar ratio – Not less than 1:1 and not more than 3:1. b) Patent & Proprietary cereal based Oral Rehydration Salts on reconstitution to one litre shall contain: total osmolarity – Not more than 2900 milliosmoles. Precooked rice-equivalent to not less than 50gm and not more than 80gm as total replacement of Dextrose. c) Patent and Proprietary Oral Rehydration Salts (ORS) may contain aminoacids in addition to Oral Rehydration Salts conforming to the parameters specified above and labeled with the indication for 'adult Choleraic Diarrhoea' only. d) Patent and Proprietary Oral Rehydration Salts shall not contain Mono or Polysaccharides or Saccharin sweetening agent. GSR No. 57(E) 07-02-1995
Additions to Gazette Notification 1995	**Issued on : 15.9.95 Issued By: Indrajit Choudhury, Addl. Secretary**	**Gazette Notification of Drug Controller of India No. X.11014/ 2/95, DMS and PFA.** 53. Fixed dose combination of Oxyphenbutazone or Phynylbutazone with any other drug GSR No. 633(E) dt. 30-09-1995 GSR No.123(E) 11-03-1996 and GSR No. 230(E) 04-06-1996 54. Fixed dose of combination of Analgin with any to other drug. GSR No. 4405(E) 03-06-1996 55. Fixed dose combination of dextropropoxyphene with any other drugs other than anti-

		spasmodics and non-steroidal anti-inflammatory drugs (NSAIDS) GSR No.4405(E) 03-06-1996 56. Fixed dose combination of a drug, standards of which are prescribed in the Second Schedule to the said Act with an Ayurvedic, Siddha or Unani Drug GSR No.4405(E) 03-06-1996
		G.S.R No.93(E) dt.25-2-1997
	Added by G.S.R No.590(E) dt.17-8-1999 **Sr No.59 & 60 omitted by G.S.R 704(E) dt 20.10.1999**	57. Parenteral preparations containing fixed dose combination of streptomycin with penicillins with effect from 01-01-1998. GSR No.499(E) 14-08-1998 58.Mepacrine Hydrochloride (Quinacrine and its salts) in any dosage form for use for female sterilization or contraception. 59.Fenfluramine and Dexfenfluramine.
	Added by G.S.R No.590(E) dt.17-8-1999. **Sr No.59 & 60 omitted by G.S.R 704(E) dt 20.10.1999**	60. Fixed dose combination of haemoglobin in any form (natural or synthetic) GSR No. 814(E) 16-12-1999 (w.e.f. 01-09-2000) 61. Fixed dose combination of Pancreatin and Pancrelipase containing amylase, protease, and lipase with any other enzyme. GSR No. 814(E) 16-12-1999 (w.e.f. 01-09-2000) **G.S.R No. 702 (E) dt.20-10-1999** 62. Fixed dose combination of Vitamin B1, Vitamin B6 and Vitamin B12 for human use with effect from 01-01-2001 **G.S.R No. 814(E) dt. 16-12-1999 (w.e.f. 01-09-2000)** 63. Fixed dose combination of haemoglobin in any form (natural or synthetic). GSR No. 814(E) 16-12-1999 (w.e.f.

		01-09-2000) 64. Fixed dose combination of Pancreatin and Pancrelipase containing amylase, protease and lipase with any other enzyme. GSR No. 814(E) 16-12-1999 (w.e.f. 01-09-2000) **G.S.R No.169(E) dt. 12-03-2001** 65. Fixed dose combination of Diazepam and Diphenhydramine Hydrochloride. **G.S.R No. 170(E) dt. 12-03-2001 (with effect from 01-01-2002)** 66. Fixed dose combination of Nitrofurantoin and trimethoprim. 67. Fixed dose combination of Phenobarbitone with any anti-asthmatic drug. 68. Fixed dose combination of Phenobarbitone with Hyoscin and/or Hyoscyamine. 69. Fixed dose combination of Phenobarbitone with Ergotamine and/or Belladona. 70. Fixed dose combination of Haloperidol with any anti-cholinergic agent including Propantheline Bromide. 71. Fixed dose combination of Nalidixic Acid with any anti-amoebic including Metronidazole. 72. Fixed dose combination of Loperamide Hydrochloride with Furazolidone. 73. Fixed dose combination of Cyproheptadine with Lysine or Peptone. 74. Astemizole. GSR No. 732(E) 29-10-2002 w.e.f. 1-8-2000 75. Terfenadine. GSR No. 191(E) dt. 5-3-2003 w.e.f. April 2003 76. Phenformin. GSR No. 780(E) dt. 1-10-2003

5 Banned Drugs

Countries, which have never allowed these drugs, and therefore do not need to ban them, are NOT listed here. Other countries, which have a legal structure, which discourages the introduction of hazardous or irrational drugs, or strong medical associations which ensure withdrawal of such drugs without their having to be banned are also NOT listed.

1. AMIDOPYRINE / (AMINOPHENAZONE AMINOPYRINE/ DIMETHYLAMINOANTIPYRINE/ IMETHYLAMINO/ PHENYLDIMETHYL/ PYRAZOLONE/ DIPYRINE)

REASON FOR BANNING: Dangerous. Can cause fatal agranulocytosis[1,1] and aplastic anaemia. Much safer and cheaper alternatives are available.

"The risk of agranulocytosis...is sufficiently great to render this drug unsuitable for use. Onset of agranulocytosis may be sudden and unpredictable".[1.2]

"Amidopyrine is considered toxic because: causes high incidence of agranulocytosis.

In some individuals it may cause a sharp fall of total leucocyte count associated with chill, fever, headache and pain in muscles and joints following the administration of drug".[1.3]

USED: For pain, fever, inflammation.

Countries where banned, withdrawn or restricted:

Australia, Austria, Belgium, Chile, Denmark, Finland, France, Greece, Italy, Japan, Kuwait, Korea, Mauritius, Nepal, Philippines, Rumania, Saudi Arabia, Singapore, Switzerland, Thailand, Turkey, Venezuela, West Germany, Yemen.

SAFER ALTERNATIVES: For fever: Paracetamol or aspirin; for pain and inflammation: aspirin.

2. FIXED DOSE COMBINATIONS OF VITAMINS WITH ANTI-INFLAMMATORY AGENTS AND TRANQUILIZERS

Drugs containing anti-inflammatory agents, tranquilizers and vitamins together though present in the market, are not listed in MIMS, CIMS or the Pharmaceutical Guide. Their presence in the market cannot be commented upon. Combinations of anti-inflammatory agents with vitamins, and tranquilizers with vitamins are listed under 'Gazette Ambiguities'.

3. FIXED DOSE COMBINATIONS OF ATROPINE / BELLADONA / HOMATROPINE/SCOPOLAMINE IN ANALGESICS AND ANTI-PYRETICS

REASONS FOR BANNING: Dangerous. Atropine may block the sweating response which helps to lower temperature, thus making the anti-pyretic (fever-reducer) less effective, leading to higher fever.

"Small doses of Atropine or scopolamine

1.1 See glossary.
1.2 Martindale: The Extra Pharmacopoeia, 28th Edition, 1982.
1.3 Drug Consultative Committee Recommendation, 1980.

inhibit the activity of sweat glands, despite the vasodilatation the drug may cause in some skin areas, the skin becomes hot and dry, sweating may be depressed enough to raise the body temperature. Nevertheless, in infants and small children moderate doses induce 'atropine fever'....Suppression of sweating is doubtless a considerable factor in the production of the fever, especially when the environmental temperature is high...."[3.1]

USED: Analgesics for pain, anti-pyretics for fever. Atropine as an anti-spasmodic and as an antidote to certain poisons, like organophosphorus insecticides.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
NEPAL [3*]

SAFER ALTERNATIVES: Painkiller (e.g. aspirin) or fever reducer (e.g. paracetamol) without atropine, or atropine alone.

4. FIXED DOSE COMBINATIONS OF STRYCHNINE AND CAFFEINE IN TONICS

This combination was available until 1985.

REASON FOR BANNING: Dangerous. Strychnine has no useful effect, and too much can cause convulsions and death. Caffeine is not useful in tonics, and is usually included in subtherapeutic (insufficient) doses.
Countries, which have never allowed these drugs, and therefore do not need to ban them, are not listed here. Other countries (also not listed) have a legal structure, which discourages the introduction of hazardous or irrational drugs.

"Strychnine has no demonstrated therapeutic value, despite a long history of unwarranted popularity."[4.1]

"There is no rational basis for the use of strychnine in therapy and therefore, no justification for the use of it in any proprietary medicine. There is a very narrow margin between the therapeutic dose and the toxic dose of strychnine."[4.2]

See page for details on Gazette Ambiguities.
USED: Caffeine and strychnine are used as stimulants. (Strychnine is considered obsolete as regards the therapeutic value).

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
Bangladesh, Canada, Italy, Nepal, Philippines and Turkey.

SAFER ALTERNATIVES: Omission of strychnine or caffeine, or better still, provision of nutritious food. As a stimulant, the therapeutic dose of caffeine is 100 mg (e.g. 2 cups of coffee).[4.3]

5. FIXED DOSE COMBINATIONS OF YOHIMBINE AND STRYCHNINE WITH TESTOSTERONE AND VITAMINS

Drugs containing yohimbine, strychnine, testosterone and vitamins together are not

4.1 Goodman & Gilman, The Pharmacological Basis of Therapeutics, 7th Edition 1985, p. 584.
4.2 Drug Consultative Committee Recommendations, 1980.
4.3 Martindale: The Extra Pharmacopoeia, 28th Edition p. 340.

3.1Goodman & Gilman, @The Pharmacological Basis of Therapeutics (Quoted) 7th Edition 1985, p. 136.
3 The fact that a given product is not listed as banned or restricted by a country does not necessarily mean that it is permitted in that country.*

listed in MIMS, CIMS and Pharmaceutical Guide. Their presence in the market cannot be commented upon. (Those containing yohimbine and strychnine separately are listed under Gazette Ambiguities).

6. FIXED DOSE COMBINATIONS OF IRON WITH STRYCHNINE, ARSENIC AND YOHIMBINE

Drugs containing iron, strychnine, arsenic and yohimbine together are not listed in MIMS, CMS or Pharmaceutical Guide. Their presence in the market cannot be commented upon. Those containing strychnine, arsenic and yohimbine separately are listed under 'Gazette Ambiguities'.

7. FIXED DOSE COMBINATIONS OF SODIUM BROMIDE/CHLORAL HYDRATE WITH OTHER DRUGS

REASON FOR BANNING: Dangerous. Sodium bromide can cause vomiting, dizziness and hallucinations. Chloral hydrate can cause stomach irritation, nightmares and confusion. Their therapeutic concentration in the blood is very close to their toxic levels and there are safer hypnotic drugs available today, so they are now obsolete.

"Bromides were formerly used for their sedative and anti-convulsant properties; they have been replaced by more effective and less toxic drugs".[7.1]

"In therapeutic doses side-effects of (chloral hydrate) include gastric irritation, light headedness, ataxia, nightmares, excitement and confusion (sometimes with paranoia)".[7.2]

USED: As sedative.

8. PHENACETIN/ ACETOPHENETIDIN/ PHENACETINIUM/ ACETOPHENETIDIDE

REASON FOR BANNING: Dangerous. Can cause liver and kidney damage, safer alternatives available, therefore obsolete.

"Prolonged administration of large doses of analgesic mixtures containing phenacetin, has been associated with the development of renal papillary necrosis' and appears to be associated with the development of transitional-cell carcinoma of the renal pelvis. Phenacetin has analgesic and antipyretic actions similar to those of aspirin".[8.1]

"Fixed dose combinations of any category of drugs with phenacetin should not be allowed, as the question of banning phenacetin because of its potential toxicity (nephropathy, methemoglobinemia, hemolytic anemia as a consequence of chronic overdosage) is under active consideration of the Government".[8.2]

USED: For pain, inflammation and fever.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
Canada, Chile, Cyprus, Denmark, Finland, Israel, Italy, Mauritius, Nepal, Nicaragua, Norway, New Zealand, Philippines, Rumania, Saudi Arabia, Sweden, Thailand, Turkey, U.K., U.S.A., Yemen.

7.1 Martindale : The Extra Pharmacopoeia, 28th Edition p.340

7.2 Ibid. p. 396 (Quoted).

8.1 Ibid. p. 271.

8.2 Drug Consultative Committee Recommendation, 1980.

SAFER ALTERNATIVES: For fever: paracetamol, for pain and inflammation: aspirin.

9. FIXED DOSE COMBINATIONS OF ANTI-HISTAMINICS WITH ANTI-DIARROHEALS

This combination was available until 1984.

REASON FOR BANNING: Dangerous. The anti-histaminic action may mask other symptoms and make accurate diagnosis and treatment difficult.

USED: Anti-histaminics for allergies; anti-diarroheals for diarrhoeas.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
Nepal[9*]

10. FIXED DOSE COMBINATIONS OF PENICILLIN AND SULPHONAMIDES

This combination was available until 1985.

REASON FOR BANNING: Dangerous. Penicillin is bactericidal (kills bacteria), whereas sulphonamides are bacteriostatic (stop bacteria multiplying), so the combination may diminish the bactericidal effects of penicillins, making them useless.

"Fixed dose combinations of penicillin with sulphonamides are irrational for the following reasons:

a) The combination of penicillin, a bactericidal drug and sulphonamides a bacteriostatic drug may cause antagonism.

b) There is a risk of development of bacterial resistance to both the drugs".[10.1]

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
Nepal

SAFER ALTERNATIVES: Penicillin or Sulphonamide, not both.

Countries, which have never allowed these drugs, and therefore do not need to ban them, are not listed here. Other countries (also not listed) have a legal structure, which discourages the introduction of hazardous or irrational drugs.

11. FIXED DOSE COMBINATIONS OF VITAMINS WITH ANALGESICS

REASON FOR BANNING: Irrational, vitamins are not painkillers, analgesics do not help in the treatment of vitamin deficiency. Combining the two only leads to unnecessary cost.
"Fixed dose combinations of high dose vitamins with analgesics should not be allowed unless there is adequate evidence in support of the rationale of such combination".[11.1]

USED: Analgesics for pain, vitamins for vitamin deficiency.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
Bangladesh, Philippines

*9*The fact that a given product is not listed as banned or restricted by a country does not necessarily mean that it is permitted in that country.*
Countries, which have never allowed these drugs, and therefore do not need to ban them, are not listed here. Other countries (also not listed) have a legal structure, which discourages the introduction of hazardous or irrational drugs.

10.1 Drug Consultative Committee Recommendations 1980.
11.1 Drug Consultative Committee Recommendations 1980. Now reformulated. Check label for contents.

RATIONAL ALTERNATIVE: Pain killer alone; or vitamins (from nutritious food if possible) for vitamin deficiency.

12. FIXED DOSE COMBINATIONS OF TETRACYCLINE/VITAMIN C

Terramycin SF contains tetracycline and vitamin B factors. It does not contain vitamin C.

REASON FOR BANNING: Irrational. Vitamin C does not help in the treatment of diseases requiring tetracycline, it only increases the cost of the drug. See also No.19 and 24.

USED: For bacterial infection.

EXAMPLE OF COMBINATIONS: Terramycin SF Cap. (Pfizer): Oxytetracycline Hcl. Vitamin B1, Vitamin B2, Niacinamide, Cal. Pantothenate, Vitamin B6, Folic acid Vitamin B12.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
Italy, Nepal, Sweden, USA, Venezuela.

RATIONAL ALTERNATIVE: Tetracycline alone (for men and non-pregnant and non-lactating women only - see 19 and 24 on Oral Tetracycline). Another antibiotic for pregnant or lactating women and children.

11.1 Drug Consultative Committee Recommendations 1980. Now reformulated. Check label for contents.

13. FIXED DOSE COMBINATIONS OF HYDROXYQUINOLINE ' GROUP OF DRUGS EXCEPT PREPARATIONS, WHICH ARE USED FOR THE TREATMENT OF DIARRHOEA AND DYSENTRY AND FOR EXTERNAL USE ONLY

All hydroxyquinoline (clioquinol) drugs on the market are intended for either diarrhoea or for external use. See also no. 50.

14. FIXED DOSE COMBINATION OF STEROIDS FOR INTERNAL USE EXCEPT COMBINATIONS OF STEROIDS WITH OTHER DRUGS FOR TREATMENT OF ASTHMA

REASONS FOR BANNING: Dangerous, steroids are powerful drugs and should only be used in carefully individualized doses, starting with a "loading dose" and then tapering off. Fixed dose combinations do not allow this tapering off, prescribers, dispensers and patients are very often unaware that a combinations contains a steroid, so that the drug if stopped abruptly leads to fall in blood pressure and kidney problems. Combinations of steroids with other drugs is irrational.

Fixed dose combination of steroids with any other category of drugs should not be allowed, as they are considered harmful for the reasons.

If the steroid is abruptly withdrawn, the adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency.

It is difficult to adjust the dose of the steroid when it is present in fixed dose combinations with other drugs.[14.1]

Empirical use of corticosteroids may mask

14.1 UN Consolidated List, 10th Edition, 2003, p. 257.*

the symptoms to such an extent that a true diagnosis becomes extremely difficult to make.[14.2]

Fixed dose combination of steroids for asthma had been excluded by the Drug Technical Advisory Board even though the Drug Consultative in 1980. The result had been that suddenly indication of steroid combinations e.g., Cortopen, Betaklor Contimal etc., had changed from allergy, insect bites, food poisoning etc. to bronchial asthma.

Hence most of the drugs that should have been banned had escaped the ban while the misuse continued.[14.3 & 14.4]

14*. FIXED DOSE COMBINATION OF CORTICOSTEROIDS WITH ANY OTHER DRUG FOR INTERNAL USE WAS BANNED IN 1988

REASONS FOR BANNING: Fixed dose combination of steroids do not allow for titration of dose, besides misleading consumer to believe that they are taking merely painkillers or bronchodilators and therefore taking them for prolonged periods without awareness of the side effects of long term steroids which are given below.
Oral anti-histamines are mainstay of treatment for urticaria, severe attack, refractory to standard therapy may require SHORT COURSE OF CORTICO STERIODS.[14*] Concurrent administration of such drug potentates adverse affects without increasing benefits.[14*.1]

Two categories of Toxic effects are observed in the therapeutic use of adrenocorticoids: those resulting from withdrawal and those resulting from continued use of large doses.

Acute adrenal insufficiency results from too rapid withdrawal of corticosteroids after prolonged therapy.

A characteristic corticosteroid withdrawal syndrome, consisting of fever, myalgia, arthralgia and malaise, may be extremely difficult to distinguish from reactivation of rheumatoid arthritis or rheumatic fever.[14*.2]

Pseudotumor cerebri and papilledema is a rare reaction that follows reduction or withdrawal of Cortiscosteroid therapy (i.e. increase in intracranial tension).[14*.3]

Process of recovery of normal pituitary and adrenal function required 9 months in some patients.

During this recovery period and for an additional 1 or 2 years, the patient may need to be protected during stressful situations, such as surgery or severe infections, by the administration of Corticosteroids.

In addition to pituitary-adrenal suppression, the principal complications resulting from prolonged therapy with corticosteroids are fluid and electrolyte disturbances; hypertension; hyperglycemia and glycosuria; increased susceptibility to

14.1 Drug Consultative Committee Recommendations 1980.
14.2 Martindale 30th Edition 1993 p. 714.
14.3 Rational Drug Policy VHAI-AIDAN 1986.
14.4 Rational Selection of Drugs VHAI 1986 (International Consultation).

infections, including tuberculosis; peptic ulcers, which may bleed, perforate; osteoporosis; a characteristic myopathy; behavioural disturbances; posterior sub-capsular, cataracts; arrest of growth; cushings habitus consisting of "moon face" "buffalo hump", enlargement of supraclavicular fat pads, "central obseisty" striae, ecchymoses, acne and hirsutism.

Myopathy characterized by weakness of the proximal musculature of arms and legs and legs of their associated shoulder and pelvic muscles is occasionally seen in patients taking large doses of corticosteroids.

It may occur soon after treatment is begun and be sufficiently severe to prevent ambulation.

Behavioural disturbances may take various forms including nervousness, insomnia, changes in mood or psyche, and psychopathies of the manic depressive or schizophrenic type. Suicidal tendencies are not uncommon.

Posterior sub-capsular cataracts have been reported in children receiving corticosteroid therapy.

Osteoporosis and vertebral compression fractures are frequent serious complications of corticosteroid therapy in patients of all ages.

Rib and vertebrae, bones with a high degree of trabecular structure, are generally the most severely affected.

*14*Martindale 33rd Edition, 2003 p. 1060@1.*

14.2Amatruda et al 1960.*

14.3Levine & Leopold, 1973.*

Unfortunately, significant loss of bone must occur before it is apparent from radiography.

Aseptic necrosis of bone (Osteonecrosis) may complicate long term therapy with glucocorticoids and has also been reported following short courses with high doses. The femoral head is most often involved, but other large joints may be affected, joint pains and stiffness may be the earliest symptoms and the syndrome.

Inhibition or arrest of growth can result from administration of relatively small doses of glucocorticoids to children and it cannot be overcome with exogenous human growth hormone.[14.4]

Fixed dose combinations of steroids should not be allowed because, if the steroid is abruptly withdrawn, the adrenal suppression accompanying prolonged steroids therapy leads to symptoms of adrenal insufficiency. It is difficult to titrate the dose of the steroid when it is present in fixed dose combinations with other drugs.[14.5]

Concurrent administration of corticosteroids will cause excessive loss of potassium.[14*6] Also it is impossible to vary the dosage or time schedule of each drug separately. If adverse effects arise it is difficult to know which drug is responsible for them.[14.7]
Corticosteroids and androgens affect the protein bound iodine.[14.8]

14.4 Goodman & Gilman: The Pharmacological Basis of Therapeutics 8th Edition Vol. II 1991 p. 1448-1452.*
14.5 Drug Consultative Committee Recommendations 1980.*
14.6 Martindale Extra Pharmacopoeia 28th Edition 1982, p. 449.*
14.7 Paris A.P. Medicines - A Guide for Everybody 5th Edition 1984, p. 29.*
*14*8 Jame P. Adverse Drug Reaction Bulletin 1972, p. 104.*

In addition to pituitary-adrenal suppression, the principal complications resulting from prolonged steroid therapy are: fluid and electrolyte disturbances, hyperglycemia and glycosuria, increased susceptibility to infections including tuberculosis, peptic ulcers (which may bleed or perforate), osteoporosis, a characteristic myopathy, behavioural disturbances, and Cushing's hibitus, consisting of "moon face", "buffalo hump", enlargement of supra clavicular fat pads, acne etc.[14.9]

Unless considered life saving, systemic administration of corticosteroid is contraindicated in patients with peptic ulcers, osteoporosis, psychoses, or severe psychoneurosis and they should be used only with great caution in the presence of congestive heart failure in patients with diabetes mellitus, infectious diseases, chronic renal failure and uraemia, and in elderly persons. Empirical use of Corticosteroid may mask the symptoms to such an extent that a true diagnosis becomes extremely difficult to make.[14*10]

COUNTRIES WHERE BANNED, WITHDRAWN OR SEVERELY RESTRICTED
Bangladesh, Turkey, Denmark, Saudi Arabia, Venezuela, Italy, Australia, Belgium, Greece, Norway, New Zealand, Singapore, Thailand, USA, India, Nepal, etc.[14*11]

Fixed dose combination of Corticosteroids with any other drug for internal use
THEOCORTINDON INDO PHARMA
SAFER ALTERNATIVES: Single steroid drug whenever needed.

*14*9 Goodman & Gilman 8th Edition 1991 p. 1448.*
*14*10 Martindale, 30th Edition 1993, p. 714.*
*14*11 Consolidated List of Products: United Nations Secretariat 37/137, 1986.*

15. FIXED DOSE COMBINATION OF CHLORAMPHENICOL FOR INTERNAL USE EXCEPT COMBINATIONS OF CHLORAMPHENICOL AND STREPTOMYCIN (1983)

REASON FOR BANNING: Changes in the peripheral blood include leukopenia, (decrease in white cell count) thrombocytopenia (decrease in platelet count) and aplasia of the bone marrow with fatal pancytopenia (fall in number of red cells, white cells and platelets).

WHO Comment: Chloramphenicol, an antibiotic isolated from Streptomyces venezuelae in 1947, first became available for general clinical use in 1948. By 1950 it was evident that its use could cause serious, sometimes fatal, blood dyscrasias. However, it remains one of the most effective antibiotics for treating invasive typhoid fever and salmonellosis, some rickettsioses and serious infections caused by Haemophilus influenzae or anaerobic organisms. This is considered to justify its retention in the WHO Model List of Essential Drugs.

Countries where banned or restricted: Spain, Hungary and Ireland.[15.1]

Resistance to chloramphenicol in S. Typhi has become a worldwide problem.
Registration of products containing chloramphenicol was disallowed because of propensity of this drug to cause aplastic anemia.[15.2]

15.1 WHTAC 1 The Use of Essential Drugs, 2nd Report of the WHO Expert Committee, 722. 1985 and UN Consolidated List, 8th Edition, 2003, p. 52.
15.2 Martindale, 33rd Edition, p. 260.

Low Benefit High Risk
Used in Typhoid (Enteric fever) Paratyphoid and misused for trivial infections and bacterial diarrhoea.

The story of Chloramphenicol - Streptomycin

In the case of **Chloramphenicol,** a patient with typhoid fever will be more likely to survive if given the drug. Chloramphenicol was an effective and cheap drug for typhoid, though potentially hazardous. But someone with a less serious bacterial infection would be unwise to risk the hazards associated with this drug when a safer alternative, such as co-trimoxazole or ampicillin, will cure the infection just as effectively. A child with diarrhoea who is given chloramphenicol is facing the risk of possible fatal side effects while gaining no benefit.

Usage of **Chloramphenicol-Streptomycin** combination can cause diarrhoea because of super infection due to change in gut flora.

Misuse of antibacterials for the common viral childhood diarrhoeas and other trivial problems for which antibacterials are not indicated has led to emergence of drug resistance.

The casual and unnecessary use of antibiotics not only harms the individual – it creates havoc in the population as a whole. Thousands of people died in Mexico in 1975 from a typhoid epidemic quite unnecessarily. Chloramphenicol had been used carelessly over the years for trivial infections like diarrhoea, allowing resistance to build up. When the outbreak occurred it was found that chloramphenicol used mainly in diarrhoea was quite useless for Typhoid.

In the Shigella dysentry endemic in West Bengal a few years ago, over 2000 people died due to resistance having emerged to most of the commonly used antibiotics. By the time the fact that drug resistance had emerged was recognized, it was too late. The answer is not more and more exotic costly antibiotics, but responsible use of what we have, leaving the exotic ones for special situations. In a country like ours, where tuberculosis is a major cause of suffering and mortality, the casual use of **streptomycin** (an essential part of low cost TB treatment) would have threatened the lives of thousands. Streptomycin was commonly given in fixed-dose combinations with penicillin or with chloramphenicol for viral infections, which could be treated better in other ways. Through this casual use, TB bacilli are given ample opportunity to develop resistance to streptomycin and the number of TB patients who fail to respond to treatment is increasing daily. The high cost of treatment of tuberculosis for the poor if they have to pay for it. Ethambutal Rifampicin makes such treatment an impossibility. Rifampicin, Ethambutal, INH are available as part of DOTS regime in districts covered under Revised National TB Strategy. It is imperative that we limit the use of streptomycin to cure diseases for which streptomycin is intended, and it will be needed for TB with emergence of drug resistance. The last anti-TB drug was

discovered 28 years ago. All anti-TB drugs should be used rationally as per the Standard Treatment Guidelines.

Hazardous drugs with limited usefulness should be very severely restricted to their specific uses. The present practice of individual patients being unnecessarily exposed to serious and sometimes fatal side effects, when safer treatment is available, should be stopped.

COUNTRIES WHERE BANNED WITHDRAWN OR RESTRICTED
Egypt, Italy, Japan, Nepal and Philippines

SAFER ALTERNATIVES: Cotrimoxazole, ampicillin and other antibiotics depending upon the cause.

15. FIXED DOSE COMBINATION OF CHRLORAMPHENICOL WITH ANY OTHER DRUG FRO INTRNAL USE WAS BANNED IN 1988

No.15 in the Banned Drug List of Gazette Notification, (3rd November) 1988.

REASON FOR BANNING: Dangerous. Chloramphenicol can cause fatal agranulocytosis[15*.1] and should therefore be used only when it is specifically indicated (e.g. for typhoid). Of all the drugs that may be responsible for pancytopenia, chloramphenicol is the most common cause. These reactions may represent an idiosyncratic reaction to the drug. The incidence is not related to dosage, however it seems to occur more commonly in individuals who undergo prolonged therapy and especially in those who are exposed to the drug on more than one occasion.[15*.2]
"(Chloramphenicol) should never be employed in diseases readily, safely and effectively treatable with other anti-microbial agents, or in undefined situations".[15*.3]

Often serious blood dyscrasias including aplastic anaemias after both short term and prolonged therapy, bone marrow suppression, grey baby syndrome in infants, G.I. upsets, optic and peripheral neuritis and allergic skin reactions can be caused by chloramphenicol. Resistance to Chloramphenicol in S Typhi has become a worldwide problem.[15*.4]

Chloramphenicol may interfere with development of immunity and it should not be given during active immunization.

Streptomycin is used for treating tuberculosis. The combination is therefore not useful at all, and only leads to the unnecessary consumption of either chloramphenicol or streptomycin, so that strains of TB become resistant to the latter, thus rendering the drug useless for TB.

Streptomycin was a drug of choice in the treatment of tuberculosis under the Standard Treatment Guidelines and should generally be reserved for this use because when used in the treatment of other bacterial infections resistance has been found to develop within 2 to 3 days. The drug should be reserved only for TB where it will be needed with the emergence of drug resistance to DOTS drugs, unless

15.1 See glossary.*

15.2 Goodman & Gilman, The Pharmacological Basis of Therapeutics, 8th Edition 1991, p. 1127.*
15.3 Ibid. p. 1129.*
15.4 Ibid. 7th Edition, 1985 p. 1183.*

Rational Drug Use and non-default are ensured. Antibiotic guidelines must be followed for ordinary infections and Standard Treatment Guidelines recommended under the National TB Control programme - RNTCP.

The combination of chloramphenicol with streptomycin was recommended for weeding out by the subcommittee of Drug Consultative Committee in 1980 for the following reason:

"Fixed dose combinations of chloramphenicol with streptomycin should not be allowed. As chloramphenicol is potentially a toxic drug, its use should be kept restricted to enteric fever only".

This combination was excluded from the Banned Drug List by the Drug Technical Advisory Board in 1982 and by the Gazette Notification of Drug Controller of India, 23rd July 1983 (p. 5).

It was later banned under the Gazette Notification of 3rd November 1988.
USED: for diarrhoea and amoebic dysentery.

COUNTRIES WHERE BANNED WITHDRAWN OR RESTRICTED:
Bangladesh, Cyprus, Denmark, Dominican Republic, Italy, Japan, Nepal, Norway, Philippines, Saudi Arabia, Sweden, Venezuela, Sri Lanka, Pakistan and Malaysia.

SAFER ALTERNATIVE: For diarrhoea, oral rehydration therapy; for amoebic dysentery, oral rehydration therapy and metronidazole; for bacillary dysentery - appropriate antibiotic along with oral rehydration therapy should be given.

16. FIXED DOSE COMBINATIONS OF ERGOT

Brand	*Manufacturer*
VASOGRAIN	LE SANTE

REASON FOR BANNING: Dangerous and irrational. Ergotamine is useful for migraine headache, and ergometrine for haemorrhage after childbirth, but they should be used very carefully in the minimum dose required, since overdose leads to gangrene and loss of limbs. Caffeine taken with ergotamine enhances the effects of ergotamine, but a fixed-dose combination is unnecessary. Prophylatic (preventive) use is hazardous because of the risk of overdose leading to gangrene.
"The usual dose (or ergotamine) is 1-2 mg administered by mouth. Not more than 6 mg should be administered in a day and not more than 10 mg in a week".[16.1]

"The ergot alkaloids are highly toxic and may cause acute or chronic poisoning...Poisoning is usually due to overdose".[16.2]

Analgesics, Antihistamines for treatment of Migraine Headache

Ergotamine is used for treatment of migraine and cluster headaches. Dosage being 1mg sublingual used at the onset of migraine. Ergotamine causes constriction of peripheral and cranial blood vessels and gives relief.[16.3]
USED: Ergotamine for migraine and

16.1 Goodman & Gilman, The Pharmacological Basis of Therapeutics, 7th Edition 1985, p. 937.
16.2 Quoted James Whang, The Essential Guide to Prescription Drug, 8th Edition 1985, p. 773.
16.3 Martindale, 33rd Edition 2002, p. 453.

vascular headache; ergometrine for severe bleeding after childbirth.
SAFER ALTERNATIVES: Ergotamine or ergometrine alone, in correct doses, course of Propranalol under Medical Guidance.

17. FIXED DOSE COMBINATIONS OF VITAMINS WITH ANTI-TB DRUGS EXCEPT COMBINATIONS OF ISONIAZIDE WITH PYRIDOXINE HYDROCHLORIDE (VIT. B6)

REASON FOR BANNING: Irrational. Isoniazide has an anti-vitamin B6 effect, therefore supplementary vitamin B6 is required when treatment includes isoniazide. This is not so for other anti-TB drugs.

USED: For tuberculosis.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
None

RATIONAL ALTERNATIVE: TB drugs alone, or with Vitamin B6 if isoniazide is used.

18. PENICILLIN SKIN/EYE OINTMENT

As far as we are able to discover, penicillin skin/eye ointment is not listed as available in the Indian market.

19. TETRACYCLINE/LIQUID ORAL PREPARATIONS

(See also No. 24, p. 39).
REASON FOR BANNING: children receiving long or short-term therapy with a tetracycline may develop brown discolourations of the teeth. Treatment of pregnant women with tetracycline may produce discolouration of the teeth in their offspring.
"Tetracyclines are deposited in the skeleton during gestation and throughout childhood. A 40% depression of bone growth has been demonstrated in premature infants treated with these agents".[19.1]

USED: For bacterial infections.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
Bangladesh, Denmark, Italy, Jordan, New Zealand, Peru, Philippines, Saudi Arabia.

SAFER ALTERNATIVES: (For children and lactating or pregnant women) another antibiotic.

20. NIALAMIDE

REASON FOR BANNING: Severe hypertensive reactions, sometimes fatal, may occur if given simultaneously with some other drugs or cheese and certain other foods.
As far as we are able to discover, nialamide is not listed as available in the Indian market.

21. PRACTOLOL

REASON FOR BANNING: Serious adverse effects on the skin, eyes, oral and nasal mucous membranes, and peritonium have been associated with practolol therapy. The changes are associated with immunological disturbances.

19.1 Goodman & Gilman, The Pharmacological Basis of Therapeutics, 8th Edition 1991, p .1122.1

As far as we are able to discover, practolol is not listed as available in the market.

22. METHAPYRILENE, ITS SALTS

Methapyrilene was available in the market until 1984.

REASONF OR BANNING: Dangerous. Can cause cancer, and there are much safer alternatives.

"It is less potent than promethazine and has a much shorter duration of action".[22.1]

USED: For inducing sleep and as an antihistaminic.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Australia, Canada, Chile, Dominican Republic, Italy, New Zealand, Philippines, Singapore, UK, USA, Venezuela, West Germany.

SAFER ALTERNATIVES: Other anti-histaminic or sleep inducing agents.

23. METHAQUALONE

(Banned under GSR 49(E) dated January 31, 1984).

REASON FOR BANNING: Risk of abuse and severe intoxication due to overdose, including lethal intoxication.

USED AS: Narcotic Psychotropic.

COUNTRIES WHERE BANNED, WITHDRAWN ON RESTRICTED: Greece, Italy, Norway, Sweden and Venezuela.

22.1 *Martindale, The Extra Pharmacopoeia, 28th* Edition p. 1315.

24. OXYTETRACYCLINE LIQUID ORAL PREPARATIONS

(Banned May 3, 1984 GSR 322(E) dealt with earlier no. 19 on p. 38)

REASON FOR BANNING: Oxytetracycline, Demeclocycline liquid oral preparations, Tetracyclines are deposited in deciduous and permanent teeth causing discoloration, enamel hypoplasia and reduced mineralisation. They are also deposited in calcifying areas in bone and the nails and when given in therapeutic doses to young infants or women during the later stages of pregnancy tetracyclines interfere with bone growth. An increase in intracranial pressure, which may be associated with a bulging fontanelle in infants has been reported in patients given tetracyclines.

25. DEMECLOCYCLINE LIQUID ORAL PREPARATION

REASON FOR BANNING: Oxytetracycline Demeclocycline liquid oral preparations Tetracyclines are deposited in deciduous and permanent teeth causing discoloration, enamel hypoplasia and reduced mineralisation. They are also deposited in calcifying areas in bone and the nails and when given in therapeutic doses to young infants or women during the later stages of pregnancy tetracyclines interfere with bone growth. An increase in intracranial pressure, which may be associated with a bulging fontanelle in infants has been reported in patients given tetracyclines.

(No drugs formulations in the market)

26. COMBINATIONS OF ANABOLIC STEROIDS WITH OTHER DRUGS

REASON FOR BANNING: Combination of anabolic steroid with other drugs. Testosterone and other androgens give rise to side effects, which can be related to their androgenic or anabolic activities. They include increase in nitrogen retention and skeletal weight, sodium and water retention, oedema, increased vascularity of skin, hypercalcaemia, and increased growth of the bone. Large and repeated doses in early puberty may cause closure of epiphyses and stop linear growth.

Elderly males may become overstimulated. Continued administration of large doses increases symptoms of virilism, such as male pattern hirsutism, deepening of the voice, atrophy of the breasts, and endometrial tissue, acne, and hypertrophy of clitoris, libido is increased and lactation suppressed in women.

The only indication for anabolic steroids is in the treatment of some aplastic anaemias and to reduce the itching of chronic biliary obstruction (in terminal care) and as such its combination with other drugs has no justification.

WHO comment: Anabolic steroids were formerly used to increase weight in-patients suffering from emaciation or debilitating diseases but have not proved totally successful. They are also used in the treatment of certain aplastic anaemias, breast cancer and in the prevention of osteoporosis. They have been subject to much abuse in athletes and malnourished children to increase body weight. Misuse in prepubertal children has been associated with undesirable effect, including precocious sexual development in males and virilization in females (development of male characteristics), which have led the Thai agency to withdraw products containing anabolic steroids indicated for increasing appetite in children.

Countries where banned or restricted: Thailand, Canada[26.1]

27. HIGH DOSE ESTROGEN PROGESTERONE COMBINATION DRUGS

Banned under No.X 11018/1/88/DMS& PFA Gazette Notification of 15th June 1988. (No. 20 in the banned drug list).

REASON FOR BANNING: Dangerous, increased risk of birth defects if taken by pregnant women. There is no indication for high dose oestrogen-progesterone combinations in gynaecology and obstetrics.

"A substantial proportion of women who are not pregnant will have their menses delayed by the administration of the hormone."[27.1]

"Normal treatment for secondary amenorrhoea: 10-20 mg oral norethisterone (weekly)."[27.2]

"These (hormonal pregnancy) tests should no longer be done".[27.3]
"Hormonal tests for pregnancy are not

26.1 UN Consolidated. List, 8th Edition, 2003, p. 24.
27.1 WHO Technical Report Series No. 657, 1981.
27.2 Ibid., p. 9.
27.3 Ibid., p. 62.

reliable. The test is false positive in one out of five women. There is also an increased risk of abnormalities".[27.4]

"Pregnant patients should not be given estrogens, particularly during the first trimester - a time when the foetal reproductive tract is developing and may be influenced by exogenous estrogens".

Hormonal pregnancy test is not only unreliable but should be condemned because of possible teratogenic effect of the progestogen used.[27.5]

In a study of the 52 mothers who had given birth to babies with congenital birth defects 31% had taken hormonal preparation during early pregnancy often with a view of terminating it.[27.6]

High dose estrogen progesterone hormonal combinations used to test the presence of pregnancy cause birth defects in high percentage of cases. This was reported in a study of the congenitally malformed babies born amongst 4291 deliveries. The study was conducted between March 1981 to February 1982 at R.N.T. Medical College, Zanana Hospital, Udaipur by Dr. M.A. Abbas.

Teratogenic effects on the unborn foetus have been observed by various researchers when the high dose Estrogen Progesterone Combination has been taken during pregnancy Spina bifida (*Dr. I. Gal)[27.7], CNS defects (Greenberg)[27.8] Cardiac defects (Dr. Arcy and Greffin), congenital heart disease[27.9] Vactreal (Vertebral, Anal, Cardiac, Tracheal, Oesophageal, Renal and Limb Defects)[27.10] Limb defect (Janerich).

There is no role for high dose estrogen progesterone combinations in gynecological practice as therapeutic agents or as diagnostic tests.[27.11]

Only a small percentage of women with secondary amenorrhoea require hormonal preparations, since in India the major cause of secondary amenorrhoea are malnutrition, anaemia, tuberculosis and psychological stress. With the advent of oral contraception, it is more appropriate to use sequential oral contraception as substitution therapy for secondary amenorrhoea.[27.12]

EP drugs case has highlighted the denial of warnings about possible teratogenic effects on unborn foetus of medicines prescribed and consumed during pregnancy, especially in the first trimester.

Submissions made during the 4 hearings on EP case with arguments and views, research studies as to why the drug should be banned are available.

USED: These drugs have been used for secondary amenorrhoea when oestrogen-progesterone hormonal deficiencies are suspected or have been diagnosed.

27.1 D. Vengada Salan et al JOG 14:348-253, 1976.

27.2 Dr. D.C. Dutta, Text Book of Obstetrics p. 73.

27.3 Dr. B. Palaniappen, Kilpauk Medical College, 1975.

27.7 Nature London, 216, 83 (1967).

27.8 Greenberg and Coworkers Hormonal pregnancy tests & congenital malformation, British Medical Journal, 2.191-2 (1975).

27.9 Heininen and coworkers Cardiovascular birth defects and antenatal exposure to female sex hormones - New England, Journal of Medicine, 296 67-70.

27.10Harlap and coworkers Birth Defects and Gestogen and Progesterones in Pregnancy-Lancet 1. 682-3.

27.11Prof. M.S. Rawlins, Prof. Clinical Pharmacology, University of New Castle upon Tyne.

27.12J.R. Newton, Novak@s Textbook of Gynecology 10th Edition, p. 260.

In India in reality these drugs are mainly misused for attempting to induce abortion and for hormonal pregnancy testing. For delaying periods for bleeding because of functional uterine haemorrhage, endometriosis etc.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Austria, Belgium, Denmark, Greece, Italy, New Zealand, Norway, Singapore, Saudi Arabia, South Africa, Thailand, U.K., U.S.A., Venezuela, West Germany.

SAFER ALTERNATIVE: Appropriate treatment after diagnosis of cause of secondary amenorrhoea (e.g. anaemia, malnutrition, stress, tuberculosis etc.)

For secondary amenorrhoea: cyclical use of estrogen and progesterone separately or use of oral contraceptives for approximately 3 cycles.

For pregnancy testing: urine test (human chorionic gonadotropin detection in urine). Clinical examination and confirmation of pregnancy based on known and well recognized physiological changes of pregnancy.

28. FIXED DOSE COMBINATION OF SEDATIVES/HYPNOTICS/ANXIOLYTICS, WITH ANALGESIC ANTIPYRETIC

REASON FOR BANNING: Analgesics are conveniently divided into two groups depending upon their efficacy. These are simple analgesics and narcotic analgesics. Simple analgesics are indicated for relief of mild pain or moderate pain and also as antipyretics. As such, there is no need of making a combination with sedative/hypnotic or anxiolytic. For severe pain, narcotic analgesics are available and there is no need to add sedatives and analgesics. Sedatives/hypnotics/anxiolytics may mask the symptoms by inducing sleep. They are habit forming and the paediatric forms may lead to accidental overdose.

Fixed dose combinations do not give the liberty of dosage according to weight.

29. FIXED DOSE COMBINATION OF PYRAZINAMIDE WITH OTHER ANTI-TUBERCULAR DRUGS EXCEPT COMBINATION AND INH AS PER RECOMMENDED DAILY DOSE GIVEN BELOW:

Drugs	*Maximum*	*Minimum*
Rifiampicin	450mg	600mg
INH	300mg	400mg
Pyrazinamide	1000mg	1500mg

REASON FOR BANNING: Major cause of tubercular treatment failure are incorrect prescribing by the physician and inadequate compliance by the patient. Avoid both excessive and inadequate dosage. Treatment should be supervised by a specialist physician (BNF No. 238 Sept. 94 p. 240)". By fixing the dosages, the wrong dosages can be avoided. Inadequate, small doses are likely to increase drug resistant tubercular bacilli.

30. FIXED DOSE COMBINATION OF HISTAMINE H2 RECEPTOR ANTAGONIST WITH ANTACIDS EXCEPT FOR THOSE COMBINATIONS APPROVED BY THE DRUG CONTROLLER OF INDIA

REASON FOR BANNING: FDC of histamine

H2 receptor antagonist with antacids... Antacids are best given one hour after food when gastric activity is at its peak. Antacids are likely to absorb other drugs and reduce their efficacy.

(This is an ambiguous form of **Gazette Notification** from which one does not know which drug combinations are approved by the Drug Controller of India).

31. THE PATENT AND PROPRIETORY MEDICINES OF FIXED DOSE COMBINATIONS OF ESSENTIAL OILS WITH ALCOHOL HAVING PERCENTAGE HIGHER THAN 20 PER CENT PROOF EXCEPT PREPARATIONS GIVEN IN THE INDIAN PHARMACOPOEIA

REASON FOR BANNING: Alcohol interacts with many important drugs and enhances the sedative/hypnotic effects of analgesic antidepressants, anti-histamines, antimuscaranics, antipsychotics, anxiolytics and hypnotics, muscle relaxants enhance the hypotensive effects of drugs like analgesics, antihypertensives, beta-blockers and nitrates, enhances hypoglycemic effects of antidiabetic drugs, enhance side effects of antiepileptics. The feeling of well being is very transient and addition of alcohol has no other long-term advantage.

32. ALL PHARMACEUTICAL PREPARATIONS CONTAINING CHLOROFORM EXCEEDING 0.5% W/W OR W/W WHICHEVER IS APPROPRIATE

REASON FOR BANNING: Chloroform is hepatotoxic and nephrotoxic. It depresses respiration and produces hypotension. Cardiac output is reduced and arrythmias may develop. Chloroform in a concentration of 0.2% is a useful preservative for extemporaneously prepared mixtures but doubts have been cast on the safety of the long term use of chloroform in mixtures and toothpastes.

Domestic manufacturers and importers have been requested to eliminate this ingredient from their marketed products since pharmacological studies have shown it to be toxic to the liver and the heart, and to be carcinogenic.[32.1]

Countries where banned or restricted: Saudi Arabia 1977, Brazil 1977, Italy 1978, Canada 1978, Norway 1978, Philippines 1978, Great Britain 1979, New Zealand 1980, Denmark 1981, Ethiopia 1981, Germany 1982, Belgium 1983, Nigeria 1985, Ireland 1989, Oman 1992, Cuba, Thailand, Venezuela.

Chloroform is not allowed in cosmetics and drug products. Since 1st February 1985 from that date, import, export and sale of products from literature of the carcinogenic effects of chloroform on animals and possible hepatotoxic and nephrotoxic effects after prolonged use by humans.[32.2]

WHO comment: Chloroform was formerly widely used in pharmaceutical preparations as a solvent and preservative as well as for its anaesthetic and flavoring properties. By the 1970s reservations concerning its safety, including positive results in carcinogenicity screening

32.1 UN Consolidated List, 8th Edition, 2003, p. 5.
32.2 AARNO Administrative Action MH 1856 15.37.112, 15 Sept. 1983.

programmes sponsored by the National Cancer Institutes in the USA had led to considerable restrictions in its use as pharmaceuticals preparations, while many pharmaceutical products containing chloroform have been withdrawn or reformulated to exclude this substance, it may still be incorporated in tooth pastes and other specified products in some countries subject to statutorily imposed concentrations limits.[32.3]

33. FIXED DOSE COMBINATION OF ETHAMBUTOL WITH INH OTHER THAN FOLLOWING:

INH 200 mg + ethambutol 600 mg
INH 300 mg + ethambutol 800 mg

REASON FOR BANNING: Side effects of ethambutol are largely confined to visual disturbances in the form of loss of acuity, colour blindness and restrictions of visual fields. The earliest feature of ocular toxicity are subjective and patients should be advised to discontinue therapy immediately if they develop deterioration in vision and promptly seek further advice. As such, a fixed dose combination with INH is not suitable for immediate discontinuation.

34. FIXED DOSE COMBINATION OF ANTIHELMINTIC, CATHARTIC/ PURGATIVES EXCEPT FOR PIPERAZINE

REASON FOR BANNING: Most of the antihelminthics have side effects viz. Abdominal pain, diarrhoea, etc. and as such there is no need of cathartic or purgatives along with them.

35. FIXED DOSE COMBINATION CONTAINING MORE THAN ONE ANTI-HISTAMINIC

REASON FOR BANNING: FDC of more than one antihistaminic. There is no evidence that anyone of the older, sedative antihistaminics is superior to any other and patients vary widely in their responses. There is no synergistic or additive effect of antihistamines, and as such FDC of more than one antihistaminic is not advisable.

Brand	*Manufacturer*
TRISTINA	MAC

36. FIXED DOSE COMBINATION OF SALBUTAMOL OR ANY OTHER BRONCHODILATOR WITH CENTRALLY ACTING ANTI-TUSSIVE AND/OR ANTI-HISTAMINE

REASON FOR BANNING: According to BNF (British National Formulary brought out annually) there is no evidence that any drug can specifically facilitate expectoration. For this reason, expectorant cough medicines have been described as "an expensive myth". Therefore there is no rationale for their use.

The drawbacks of prescribing cough suppressants are rarely outweighed by the benefits of treatment and only occasionally are they useful, as for example, if sleep is disturbed by a dry cough. Cough suppressants may cause sputum retention and this may be harmful in patients with chronic bronchitis and bronchiectasis. Though commonly used in acute bronchitis and pneumonia, they can be

32.3 IARCCD Chloroform IARC Monograph 20 (20) 401 & 427, 1979 and UN Consolidated List, 8th Edition, 2003, p. 5.

harmful; such conditions are best treated by prompt administration of antibacterial drugs. Cough suppressants such as codeine, dextromethorpan and pholcodine are seldom sufficiently potent to be effective and all tend to cause constipation. The use of cough suppressants containing codeine or similar opioid analgesics is not generally recommended in children and should be avoided altogether in those under one year of age.

Compound cough preparations have no place in the treatment of respiratory disorders, and such preparations are to be deprecated not only as irrational but also for leading to patients receiving inappropriate drugs. See also No. 39-40, P. 55 and 56.

Cough mixtures with ephedrine, antihistaminic, analgesis etc.

37. FIXED DOSE COMBINATION OF LAXATIVE AND/OR ANTI-SPASMODIC DRUGS IN ENZYME PREPARATIONS

REASON FOR BANNING: Laxatives/ antispasmodic with enzymes Enzyme preparations are normally given for dyspepsia and addition of laxatives and/ or antispasmodics are likely to be habit forming.

Excepting pancreatin there are no real enzyme preparations, and most of them are destroyed in acidic medium of the stomach.

Brands not available in the market.

38.FIXED DOSE COMBINATION OF METOCLOPRAMIDE WITH OTHER DRUGS EXCEPT FOR PREPARATIONS CONTAINING METOCLOPRAMIDE AND ASPIRIN/PARACETAMOL

REASONS FOR BANNING: Metoclopramide is primarily indicated for nausea and vomiting, particularly in gastro-intestinal disorders and treatment with cytotoxics or radiotherapy.

In migraine, because headache is associated with vomiting, a FDC of metoclopramide with paracetamol may be permissible. Besides, it increases absorptions of aspirin and paracetamol. It adversely interacts with other drugs- antagonism of effect of antimuscarinics on gastro-intestinal activity, increases risk of extrapyramidal effects with antipsychotics.

Drugs not available in the market.

39. FIXED DOSE COMBINATION OF CENTRALLY ACTING ANTI-TUSSIVE WITH ANTIHISTAMINE HAVING HIGH ATROPINE LIKE ACTIVITY IN EXPECTORANTS

The drawbacks of prescribing cough suppressants are rarely outweighed by the benefits of treatment and only occasionally are they useful, as for example, if sleep is disturbed by a dry cough. Cough suppressants may cause sputum retention and this may be harmful, in patients with chronic bronchitis and bronchiectasis. Though commonly used in acute bronchitis and pneumonia, they can be harmful, such conditions are best treated

by prompt administration of antibacterial drugs. Cough suppressants such as codeine, dextromethorpan and pholcodine are seldom sufficient potent to be effective and all tend to cause constipation. The use of cough suppressants containing codeine or similar opioid analgesics is not generally recommended in children and should be avoided altogether in those under one year of age.

Compound cough preparations have no place in the treatment of respiratory disorders, and such preparations are to be deprecated not only as irrational but also for leading to patients receiving inappropriate drugs.

A number of drugs are known to reduce cough as a result of their central actions, although the exact mechanisms are still not entirely clear. Included among them are the opioid analgesics like codeine, hydrocodeine, and hydromorphan. Noscapine is a naturally occurring opium alkaloid of the benzylisoquinoine group; except for its anti-tussive effect, it has no significant action on the CNS in doses within the therapeutic range... Other drugs that have been used as centrally acting anti-tussives include carbetapentane, caramiphen, chlophedianol, diphenhydramine and glaucine. The mechanism of action of diphenhydramine, an antihistamine is unclear. Although sedative effects are common paradoxical excitement may be seen in infants; dryness of mucous membranes due to anticholineragic effects and thickening of mucous may be a disadvantage.[39.1]

Although H1 blocking drugs have long been used in elixirs and syrups for controlling cough, especially in asthmatic children, any benefit from their specific antiallergic action or sedation may be offset by the anticholinergic properties of these drugs, which by excessive drying of the respiratory tree, can render bronchial secretion viscid and make expectoration difficult.[39.2]

Drugs available in the market.

Brand	***Manufacturer***
ALTEC	LYKA
ALTEC P	LYKA
BRONOLAX	ALKEM
C-KOF	DWD
CODOKUFF	GERMAN REMEDIES
CODYLEX LINCTUS	AFD
COLFRIN	DYNAMIC LABS
COREX	PFIZER
COSCOPIN LINCTUS	BIOLOGICAL E
COSCOPIN PLUS	CFL
DRISTAN EXPECTORANT	WYETH LEDERLE
EXIPLON	KHANDELWAL
FENDYL	NICHOLAS
IPHAREX	NATIONAL CHEMICAL AND PHARMA
MITS LINCTUS CODEINAE CO	ASTRA ZENECA
NEOFEBRIN	NEO PHARMA
NOSCAPHENE	MEDOZ PHARMA
OSCODIN	OSPER PHARMA
PHENSEDYL LINCTUS	NICHOLAS
PROCODYL	FRANKLIN LAB
SUDOHIST DMR	HAMAX PHARMA
SUPKOF	OBSURGE BIOTECH
SYNABRON D	CONCEPT
TACOF	STANMARK PHARMA
TERCUF PD	NINE FORMULATIONS
TIXYLIX	NICHOLAS
TOSSEX	SPPL ETHICAL DIV.
TOSSEX S	SPPL ETHICAL DIV.
TOX DCP	BENNET
TRAXIN D	DRAKT INTERNATIONAL

39.1Goodman & Gilman, 10th Edition, p. 528.

39.2Goodman & Gilman, 10th Edition, p. 623.

TRIATUSSIC	WANDER
TRICODEINE LICTUS	USV
TUFCUF	LOGOS PHARMA
TUSCOF	MEDINOVA LAB
TUSKON	ALPHA DRUGS AND PHARMA
TUSP	ALDE
TUSPRESS	INDOCO
TUSSIVIL D	WYETH LEDERLE
TUSQU D	BLUE CROSS
TUSQ-D	BLUE CROSS
TUXYNE	FRANCO INDIAN
TYSPRO D	PHARMA VISION
VISCODYNE D	MERIND
WYTUS	WILCURE
XEROC D	PRG PHARMA
XL 90	DWD
XL 90 COFGEL	DWD
XPECT A	ALKEM
ZED D C	STANFORD BIOTECH
ZED	STANFORD BIOTECH
ZEPDYL	MANDAR PHARMA
ZIMBA	SUN
ZYNTUS D	ZOTA PHARMA[39.3]

New Additions[39.4]

DEXOMINE	COSMAS
EUROCOF	EUROMED LAB
REKOF	REKVINA
SEUDONIT	SIGNIT

GSR No. 395(E) dt. 19-5-1999 shows that even after 5 years the banned drug combination is being permitted by State Drug Authorities.

40. PREPARATIONS CLAIMING TO COMBAT COUGH ASSOCIATED WITH ASTHMA CONTAINING CENTRALLY ACTING ANTI-TUSSIVE AND/OR ANTIHISTAMINE

Cough and cold preparations containing various combinations' of cough suppressants and expectorants together with sympathomimetics antihistamines analgesics are available. Some of these combinations such as cough suppressants and expectorant are illogical and there is little evidence to support their efficacy.[40.1]

Brand	***Manufacturer***
ACTIFED-DM	GLAXO SMITHKLINE
AGRUS	PROFIC ORGANIC
AGRUS-NS	PROFIC ORGANIC
ALERPECT	THEMIS
ALEX –P	LYKA
ALEX COUGH FORMULA	LYKA
ALTEC	LYKA
ALTEC P	LYKA
ASCORIL - D	GLENMARK
ATUS-D	ATOZ PHARMA
BESTORIL C	BESTOCHEM
BIOTRYL AT	MEDICAMEN BIOTECH
BRONCHOLYN-D	EAST AFRICAN
BRONOLAX	ALKEM
C-KOF	DWD
CADICOFF	CADILA PHARMA
CARECOF	WINCARE REMEDIES
CELKOF	CELTINE PHARMA
CHERICOF SOFGELS	STANCARE
CHERICOF COUGH FORMULA	STANCARE
CHESTON CS	PROTEC
CINCOF P	BIOCIN H CARE
CLEDEX	PANJON PHARMA
CODOKUFF	GERMAN REMEDIES
CODYLEX PLUS	AFD
CODYLEX LINCTUS	AFD
COFNIL PLUS	S G PHARMA
COFURA – DMR	PANJON PHARMA
COLDARIV	EAST AFRICAN R
COLFRIN	DYNAMIC LABS
COREX	PFIZER
COREX DX	PFIZER
COSCOPIN LINCTUS	BIOLOGICAL E
COSCOPIN PLUS	BIOLOGICAL E
COSYP	CFL
COTUS BR	DCM LAB
COTUSS	REXTAR
COXOF-D	CADEX LAB
CUF DEX	WAVES BIO TECH
DELETUS – D	NICHOLAS
DEMINE	ARMOUR REMEDIES
DENITUS - D	DEW DROPS LAB

39.3 Drug Today, Jan.-Mar. 2004, p. 462-487.

39.4 Drug Today, Apr.-June 2004, p. 782.

DERIL	SYNOKEM	PEDICOOL	BIPL
DEX	HELAX HEALTH CARE	PHENSEDYL-DM	NICHOLAS
DEXIL	CREST PHARMA	PHENSEDYL LINCTUS	NICHOLAS
DEXTRIL	PANGEA PHARMA	PIRIL-DX	JENBURKT
DM	MARS	PROCODYL	FRANKLIN LAB
DM-P3	MARS	PROTUSSA PLUS	LENBROOOK (KNOLL)
DRIKO	ALTAR HEALTH CARE		
DRISTAN EXPECTORANT	WYETH LDERKL	QUAD-D	SRI BIOTECH & PHARMA
ELTUSS	ELDER		
EMIHIST	MAITRI HEALTH CARE	RAPTUS	ADROIT H CARE
EPHEDREX	ALEMBIC	RESFREE	ALLIANZ HEALTH CARE
EXCO-PD	G NINE MARKETING		
EXIPLON	KHANDELWAL	RESIPAX TOTAL	BIPL
EXIPLON-DM	KHANDELWAL	RESPIRA-D	GENO PHARMA
FENDYL	NICHOLAS	RESPREN	JOHNSON AND JOHNSON
FLUCUF	LOGOS PHARMA		
FLUZET	REXEL	RESTCOF	ROYAL LABS
FRANKLOR PLUS	FRANKLIN LAB	SECRON – 3	PANJON PHARMA
FRANKLOR PLUS	FRANKLIN LAB	SEDORIL DCP	PHARMASYNTH
GRILINCTUS	FRANCO INDIAN	SEDOSOLVIN	IPCA
GRILINCTUS SOFTCAPS	FRANCO INDIAN	SINEX DMR	ZEE LAB
HISTAKOF	KOPRAN	SINOCLEAR	CAMLIN
HISTRIN	BROOKS PHARMA	SIOCOF	CURE QUICK PHARMA
INSTUS DRY	OCHOA		
IPHAREX	NATIONAL CHEMICAL AND PHARMA	SINEX	SANBURY
		STANCOLD	STANFORD BIOTECH
JELLICOR	PFIZER	SUDIN	GROUP
KOF D	MARK REMEDIES PVT LTD	SUDOHIST DMR	HAMAX PHARMA
		SUPKOF	OBSURGE BIOTECH
KOFGARD	MAPRA	SYNABRON D	CONCEPT
LYRAX	EAST AFRICAN ®	TACOF	STANMARK PHARMA
METUS	MERCURY HEALTH CARE	TERCUF PD	NINE FORMULATIONS
MIT'S LINCTUS-D	ASTRA ZENECA	TIXYLIX	NICHOLAS
MITS LINCTUS-DX	ASTRA ZENECA	TOSSEX	SPPL ETHICAL DIV.
MITS LINCTUS CODEINAE CO	ASTRA ZENECA	TOSSEX S	SPPL ETHICAL DIV.
NASCORE PLUS	GLENMARK	TOX DCP	BENNET
NBLOX	NB PHARMA	TRAXIN D	DRAKT
NEOFEBRIN	NEO PHARMA	TRIATUSSIC	INTERNATIONAL WANDER
NO COF AND COLD	SAIN MEDICAMENTS	TRICODEINE LICTUS	USV
NORVENT – D	INDCHEMIE	TUFCUF	LOGOS PHARMA
NOSCAPHENE	MEDOZ PHARMA	TUSCOF	MEDINOVA LAB
NUTUSS	DR ALSON LAB	TUSKON	ALPHA DRUGS AND PHARMA
ORNEX	RICHLYNS H CARE		
OSCODIN	OSPER PHARMA	TUSP	ALDE
PD-5	BIPL (RADICO REMEDIES)	TUSPRESS	INDOCO
		TUSSIVIL D	WYETH LEDERLE
PEDIA – 3	JOHNSON AND JOHNSON	TUSQU D	BLUE CROSS
		TUSQ-D	BLUE CROSS

40.1 Martindale 33rd Edition, 2002, 1082-2.

TUXYNE	FRANCO INDIAN
TYSPRO D	PHARMA VISION
VISCODYNE D	MERIND
WYTUS	WILCURE
XEROC D	PRG PHARMA
XL 90	DWD
XL 90 COFGEL	DWD
XPECT A	ALKEM
ZED D C	STANFORD BIOTECH
ZED	STANFORD BIOTECH
ZEPDYL	MANDAR PHARMA
ZIMBA	SUN
ZYNTUS D	ZOTA PHARMA

REASON FOR BANNING: According to BNF there is no evidence that any drug can specifically facilitate expectoration. For this reason, expectorant cough medicines have been described as: «an expensive myth». Therefore there is no rationale for their use.

The drawbacks of prescribing cough suppressants are rarely outweighed by the benefits of treatment and only occasionally are they useful, as for example, if sleep is disturbed by a dry cough. Cough suppressants may cause sputum retention and this may be harmful in patients with chronic bronchitis and bronchiectasis. Though commonly used in acute bronchitis and pneumonia, they can be harmful; such conditions are best treated by prompt administration of antibacterial drugs. Cough suppressants such as codeine, dextromethorpan and pholcodine are seldom sufficiently potent to be effective and all tend to cause constipation. The use of cough suppressants containing codeine or similar opioid analgesics is not generally recommended in children and should be avoided altogether in those under one year of age.

Compound cough preparations have no place in the treatment of respiratory disorders, and such preparations are to be deprecated not only as irrational but also for leading to patients receiving inappropriate drugs.

41. LIQUID ORAL TONIC PREPARATIONS CONTAINING GLYCEROPHOSPHATES AND/OR OTHER PHOSPHATES AND/OR CENTRAL NERVOUS SYSTEM STIMULANT AND SUCH PREPARATIONS CONTAINING ALCOHOL MORE THAN 20 PER CENT

REASON FOR BANNING: The glycerophosphates were introduced into medicine on the ground that lecithin contains phosphorus in the form of glycerophosphate radical and that these compounds would be more easily assimilated by the tissues, particularly by the brain. There is no evidence to support this assumption.

Brand	*Manufacturer*
PHOSPHOMIN IRON	SPPL ETHICAL DIVISION
KINETONE PLUS	LEN BROOK (ABBOTT)

42. FIXED DOSE COMBINATION CONTAINING PECTIN AND/OR KAOLIN WITH ANY DRUG WHICH IS SYSTEMATICALLY ABSORBED FROM GI TRACT EXCEPT FOR COMBINATIONS OF PECTIN AND/OR KAOLIN WITH DRUGS NOT SYSTEMICALLY ABSORBED

Combination drugs not available in the market.

REASON FOR BANNING: Absorbents such as Kaolin and Pectin are not recommended for such diarrhoeas. The first line of treatment in acute diarrhoea, as in gastroenteritis is prevention or treatment of fluid and electrolyte depletion. The absorbent properties of Kaolin and Pectin may influence the gastro-intestinal absorption of other drugs and hence its combination with other soluble drugs is not advisable.

Brands not available in the market.

WHO Comment: Kaolin, a hydrated aluminium silicate, is an absorbent and has been used to treat diarrhoea because of its ability to bind and inactivate bacterial toxins. However, it has been shown to induce only a slight change in stool consistency and there is no evidence that it can reduce the duration or the severity of diarrhoeal disease. It does not reduce fluid and electrolyte losses. It cannot be recommended in the treatment of diarrhoea.

Country banned: India, Sri Lanka[42.1]

43. CHLORAL HYDRATE AS A DRUG

REASON FOR BANNING: Chloral hydrate is corrosive to skin and mucous membranes unless well diluted and may cause gastritis with nausea and vomiting. Allergic skin reactions very occasionally occur from several hours to 10 days after a dose. Better sedative and hypnotics are available.

Not available in the market.

44. COSMETICS AND ALL AYURVEDIC DRUGS LICENSED AS TOOTH PASTES/ TOOTH POWDERS CONTAINING TOBACCO HAVE BEEN PROHIBITED WITH IMMEDIATE EFFECT No. GSR 444(E) dt. 30.4.1992

REASON FOR BANNING: Is habit forming and the paste and powders applied to teeth are likely to be kept in mouth for longer periods causing irritation and likelihood of mouth cancers.

Drugs prohibited for manufacture, sale and distribution under notifications. Tobacco usage orally has been associated with high incidence of oral cancer, throat cancer surgical resection of throat and mouth cancer is difficult this is even more common than lung cancer, oral tobacco is also known to cause severe fibrosis preventing the mouth to open, making even swallowing difficult.

This category serial no. 44 as given earlier is now replaced by Dovers Salt in the DCGI Website.

45. DOVERS POWDER/DOVERS POWDER TABLET

REASON FOR BANNING: Dover's powder contains opium that is habit forming. It is likely to paralyse intestines in children resulting in absorption of toxins and worsening the child's condition.

Not available in the market.

46. ANTIDIARRHOEAL FORMULATION CONTAINING KAOLIN, PECTIN OR ATTAPULGITE OR ACTIVATED CHARCOAL

42.1. UN Consolidated List, 8th Edition, 2003, p. 123.

REASON FOR BANNING: Absorbents such as Kaolin and Pectin are not recommended for acute diarrhoeas. The first line of treatment in acute diarrhoea, as in gastroenteritis is prevention or treatment of fluid and electrolyte depletion. The absorbent properties of Kaolin and Pectin may influence the gastro-intestinal absorption of other drugs and hence its combination with other soluble drugs is not advisable.

WHO Comment: Kaolin, a hydrated aluminium silicate, is an absorbent and has been used to treat diarrhoea because of its ability to bind and inactivate bacterial toxins. However, it has been shown to induce only a slight change in stool consistency and there is no evidence that it can reduce the duration or the severity of diarrhoeal disease. It does not reduce fluid and electrolyte losses. It cannot be recommended in the treatment of diarrhoea.[46.1]

Brands not available in the market.

The wording is defective as it means all Kaolin or Pectin containing combinations are banned. But in item No. 42 it says Kaolin and Pectin with absorbable antidiarrhoeals is allowed.

47. ANTIDIARRHOEAL FORMULATION CONTAINING PHTHALYL SULPHATHIOZOLE, OR SULPHAGUANIDINE OR SUCCINYL SULPHATHIOZOLE

REASON FOR BANNING: Insoluble sulphas: The value of insoluble sulphas in the treatment and prevention, intestinal infection is limited by the increasing resistance of enteric bacteria. Prolonged use may lead to overgrowth of candid spp.

The first line of treatment in acute diarrhoea, as in gastroenteritis, is prevention or treatment of fluids and electrolyte imbalance. In bacillary dysentery the use of appropriate antibiotic be preferred.

Because of the frequency of resistant strains, the sulfonamides are now only infrequently useful in management of bacillary dysentery (Shigella diarrhoea).[47.1]

Brands	*Manufacturer*
ENTEROGUANIDINE	ALBERT DAVID

48. ANTIDIARRHOEAL FORMULATION CONTAINING NEOMYCIN OR STREPTOMYCIN OR DIHYDROSTREPTOMYCIN INCLUDING THEIR RESPECTIVE SALTS AND ESTERS

REASON FOR BANNING: Streptomycin is mainly used in the treatment of tuberculosis. Streptomycin is rarely used in the treatment of non-tuberculosis infections due to organisms sensitive to other antibiotics. The oral use of streptomycin for treatment of intestinal infections has been dropped in Martindale 3rd edition, 1993.

Many strains of bacteria initially sensitive to streptomycin become resistant during therapy and this resistance may develop very rapidly. Resistance to streptomycin in non-tuberculosis infections may develop within two or three days of instituting treatment, whereas in tuberculosis the

46.1 UN Consolidated List, 8th Edition, 2003, p. 123.

slower rate of multiplication of the infecting organism may delay development of complete resistance for 6 weeks or more.

There is complete cross-resistance between streptomycin and dihydrostreptomycin, and partial cross-resistance between streptomycin, neomycin, kanamycin and paronomycin.[48.1]

Neomycin can only be used for infection of the skin or mucous membrane or to reduce the bacterial population of the colon prior to bowel surgery or in hepatic failure. Oral administration may lead to malabsorption.[48.2]

The most important biological effects resulting from the oral administration of neomycin are intestinal malabsorption and superinfection. Individuals treated with 4 to 6g of the drug by mouth per day sometimes develop a spruelike syndrome with diarrhoea, steatorrhea. The outstanding example of drug-induced malabsorption is that caused by neomycin. In man, the drug produces moderate malabsorption syndrome for a variety of substances, including far, protein, cholesterol, carotene, glucose, lactose, sodium, calcium, cyanocobalamine, and iron.[48.3]

As such there is no role of neomycin for treatment of diarrhoea and certainly not in fixed dose combination with other antibiotics.

Brands available in the market:

Brands	*Manufacturer*	*Content*
IMOSEC-S	Johnson & Johnson	Loperamide +streptomycin

49. LIQUID ORAL ANTIDIARRHOEALS OR ANY OTHER DOSAGE FORM FOR PAEDIATRIC USE CONTAINING DIPHENOXYLATE OR LOPERAMIDE OR ATROPINE, OR BELLADONA INCLUDING THEIR SALTS OR ESTERS OR METABOLITES, HYOSCYMINE OR THEIR EXTRACTS OR THEIR ALKALOIDS

REASON FOR BANNING: The presence of subclinical doses of atropine sulphate in preparations containing diphenoxylate may give rise to the side effects of atropine in susceptible individuals or in overdosage. The intestinal paralyzing effect of diphenoxylate and loperamide particularly in infants and children is likely to result in absorption of the intestinal toxins (bacterial) leading to death.[49.1] These products delay the elimination from the body of the organisms that cause the diarrhoea, and may prolong illness.[49.2]

Death due to respiratory distress resulting from paralysis of diaphram and the respiratory muscles is known to occur in children due to accidental overdose of gut paralysers.[49.3]

Can produce CNS effect when used in higher doses (40-60mg) and therefore has a potential for abuse and or addiction.

With excessive use or overdose constipation and (in inflammatory condition of the colon) toxic megacolon may develop.[49.4]

47.1 *Goodman & Gilman, 8th Edition, 1991, p. 1103.*

48.1 *Martindale 27th Edition, 1977, p. 1183.*

48.2 *BNF, p. 32 245.*

48.3 *Goodman & Gilman 7th Edition, 1988, p. 1166.*

The first line of treatment in acute diarrhoea, or in gastroenteritis, is prevention or treatment of fluid and electrolyte depletion. This is particularly important in infants and in frail and elderly patients.

In acute diarrhoeas anti-motility drugs like loperamide or diphenoxylate have a very limited role as adjuncts to fluid and electrolyte replacements.[49.5]

If bacterial infection is present, the antimotility drugs are likely to reduce the intestinal movement and thereby retain the infection in the guts for a long time.This is particularly dangerous for children and hence the pediatric forms have to be discouraged.

Brands	***Manufacturer***
Andial Liquid	Citadel
Emantid - M	MM Labs

50. LIQUID ORAL ANTI-DIARRHOEALS ANY OTHER DOSAGE FORM FOR PAEDIATRIC USE CONTAINING HALOGENATED HYDROXYQUINOLINES

Brands not available in the market.

CLIOQUINOL/HYDROXYQUINOLINE/
QUINIDOCHLOR/CHINOFORM/
CHLORPOPDIOQUIN/VIOFORMO/
CLIOCHINOLUM/
IODOCHLOROHYDROXYQUIN/
IODOCHLOROHYDROXYQUINOLINE/DI-
IODOHYDROXYQUINOLIN
CLIOQUINOLS (Hydroxyquinolines)

REASON FOR BANNING: Dangerous. Causes SMON, a painful nerve disease which causes limb paralysis, blindness and lack of bladder control. Effective and safer anti-amoebic drugs are available.

"Clioquinol has caused thousands of cases of SMON in Japan and elsewhere. A condition involving continuous pain, paralysis, blindness and, in extreme cases, death".

"There is no convincing evidence to suggest that...clioquinol is effective in the prophylaxis of travellers' diarrhoea".
"Hydroxyquinolines are active only on organisms present within the intestinal lumen. Used alone, there, they are active only in the absence of significant tissue invasion - a development that cannot be excluded with certainty even in patterns with asymptomatic amoebiasis".

Diodohydroxyquin and iodochlorohydroxyquin have widely and all too often been indiscriminately employed for the treatment of diarrhoea. The use of these drugs particularly at high doses for prolonged periods is unfortunately associated with significant risk. Administration of diodohydroxyquin in high doses to children with chronic diarrhoea, for example, has been associated with optic atrophy, permanent loss of vision.

Broxyquinoline has exactly the same properties concerning toxicities and

49.1Taste of Tears, VHAI, 1984.
49.2Rational Use of anti-diarrhoeals, UNICEF, WHO.
49.3Taste of Tears, VHAI, 1984.
49.4Goodman & Gilman, 10th Edition, 2003, p.1040.
49.5BNF, No. 32 p. 41 and 42.

there are cases in Sweden with exactly the same clinical picture as the clioquinol cases. So there is nothing to say that there are any differences in the toxicity of the different halogenated oxyquinolines.

Antimicrobial drugs are not indicated for the routine treatment of acute diarrhoea. Their indiscriminate use must be discouraged not only because they are often of no value, but they are needlessly expensive and can also be harmful.

It was suggested that the Japanese epidemic might be due to genetic susceptibility but a few similar cases of SMON have been reported from several other countries in association with clioquinol or related hydroxyqinoline derivatives, such as broxyquinoline or di-iodohydroxyquinoline. Oral preparations of clioquinol have now been banned in most countries.

WHO Comment: Clioquinol, a halogenated hydroxy-quinoline derivative, was introduced into medicine around 1900 as a topical antiseptic and in 1934 oral preparations for the treatment of amoebic dysentery and simple diarrhoea became available. By 1964 its use in Japan had been associated with cases of sub-acute myelo-optic neuropathy (SMON) which reached epidemic proportions resulting in its withdrawal there in 1970. Although relatively few of SMON were documented elsewhere, clioquinol was subsequently withdrawn from use in many countries and placed under prescription control in others. It was phased out worldwide by the major manufacturer between 1983 and 1985 on grounds of obsolescence. No adequately controlled evidence was ever generated to demonstrate that clioquinol is effective in bacterial or viral diarrhoea. However, products containing clioqinol and related halogenated hydroxyquinolines continue to be used in some tropical and subtropical countries where amoebiasis remains endemic. Other amoebocides are preferred in the WHO Model List of Essential drugs.[50.1]

Countries where banned/restricted:

Japan, 1970, Norway, 1974, Sweden 1975, Belgium 1976, Germany 1977, France, 1978, Argentina, 1981, Nigeria 1982, Bangladesh 1982, Philippines 1982, Italy 1983, Nepal 1983, Dorminican Republic 1983, Zimbabwe 1983, Hongkong 1984, Ethiopia 1984, Honduras 1985, Oman 1987, Pakistan 1988, Ghana 1989, Libya 1990, Bahrain, Chile, Cuba, New Zealand, Saudi Arabia, Thailand, Venezuela.[50.2]

Para 1 Grounds for decision for banning[50.3]

USED: For diarrhoea and amoebic dysentery.

REASON FOR BANNING: All the hydroxyquinolines carry a high risk of adverse effects and most experts agree that their use should be avoided because they are ineffective and dangerous. Majority of the infant and childhood diarrhoea is due of viral origin and hydroxyquinoline plays no advantage in treatment of such diarrhoeas.

COUNTRIES WHERE BANNED OR SEVERELY RESTRICTED

1970 Japan (Banned)
1974 Norway (Banned)
1975 Sweden (Banned)
1976 German Democratic Republic (Restricted)
1978 Denmark (Banned), Bangladesh (Banned), Philippines (Banned)
1983 Italy (Banned), Nepal (Banned), Dominican Republic (Banned), Zimbabwe (Banned), Zambia.
1985 Switzerland, Cuba, Federal Republic of Germany, Spain (Banned), France (Restricted), Netherlands, Saudi Arabia and Venezuela, Ethiopia (Banned), Hong Kong (Banned), Nigeria (Banned), Honduras (Banned), India's neighbouring countries, Nepal, Bangladesh, Sri Lanka and Malaysia have banned this drug.

Parke Davis who consider themselves pioneers in sales of this combination for diarrhoea have, in view of the increasing medical evidence against its use, voluntarily withdrawn their products, mexaform and enterovioform from the world market.

1987 Oman (Banned)
1988 Pakistan (Banned), Chile (Banned)
1989 Ghana (Banned), Cuba (Banned)
1990 Libya (Banned in children) Netherlands (Banned), Bahrain (Banned), Thailand (Severely Restricted), Venezuela (Restricted)

SAFER ALTERNATIVES: For diarrhoea oral rehydration therapy. For amoebic dysentery oral rehydration therapy and metronidazole.

51. FIXED DOSE COMBINATIONS OF ANTIDIARRHOEALS WITH ELECTROLYTES

REASON FOR BANNING: WHO has no doubt about the role of antidiarrhoeal products. "There are no drugs available at present that will safely and effectively stop diarrhoea. Most medicines for diarrhoea are either useless or harmful". ORT is effective in preventing and treating almost all cases of dehydration from acute watery (non-bloody) diarrhoea, including cholera. As such there is no advantage in combining on antidiarrhoeal with electrolyte solution besides, some of their antidiarrhoeals are likely to absorb the electrolytes.

Brands not available in the market.

52. PATENT AND PROPRIETARY ORAL REHYDRATION SALTS OTHER THAN THOSE CONFORMING TO THE SPECIFIED PARAMETERS

Parameters not specified, but there are many brands available that are not according to the WHO specifications.

REASON FOR BANNING: Home made Oral rehydration solutions lower in sodium (35-60 mmol/litre) and higher in glucose (upto 200 mmol/litre) than the WHO formulation may be of benefit for mild to moderate diarrhoea, when the body's homeostatic mechanisms are still working and will not be harmful, but they may be suboptimal in correction of fluid loss and electrolyte imbalance. In the more severe diarrhoeas

50.1UN Consolidated List, 8th Edition, 2003, p. 53.
50.2(WHODI) WHO Drug Information 77.1.9 1977 and UN Consolidated List, 8th Edition, 2003, p. 63.
50.3UN Consolidated List of Products - Complete 8th Edition 2003.

the WHO formulation is more effective in correcting dehydration, it carries no danger of hypernatremia if used correctly.
Sugar is required for the absorption of electrolytes but high concentrations of glucose can cause osmotic diarrhoea and exacerbate existing diarrhoea. This can occur when the sugar content in the ORS is high as in some commercial ORS packets or if mixing is improper i.e. use of more powder and less water. Since the ORS packet sizes differ so much.[52.1]

Improper mixing of ORS packet can result in more salt intake and can cause hypernatremia, which presents as irritability, mental confusion, convulsions, twitching, irregular respiration, stupor and eventually coma.[52.2]

(a) Patent and Proprietary oral Rehydration Salts on reconstitution to one litre shall contain:

Sodium - 50 to 90 milliosmoles
Total osmolarity — 240 to 290 milliosmoles
Dextrose: Sodium molar ratio — Not less than 1:1 and not more than 3:1

(b) Patent and Proprietary cereal based Oral Rehydration Salts on reconstitution to one litre shall contain:

Sodium - 50 to 90 millimoles
Total osmolarity — Not more than 290 milli osmoles
Precooked rice — Equivalent to not less than 50 gms and not more than 80 gms as total replacement of Dextrose.

(c) Patent and Proprietary Oral Rehydration Salts (ORS) may contain aminoacids in addition to Oral Rehydration Salt conforming to the parameters specified above and labeled with the indication of "Adult Cholorric Diarrhoea only".

(d) Patent and Proprietary Oral Rehydration Salts shall not contain mono or polysaccharides or saccharin sweetening agents.

The constituents of ORS packets should be the one in the WHO's essential drugs list. ORS packets are available in the market not following the prescribed ORS constituents should be banned because of the following reasons:

1. The glucose concentration is more than 20 gm per litre as such solutions can cause osmotic diuresis and more dehydration.
2. Flavour and colour may be harmful as it may cause respiratory allergy.
3. Undesirable constituents viz. Minerals etc are added which are not required and thus are useless and irrational.
4. The ORS packets should be standardized and have a uniform dose packing.
5. High costs.

Examples of Irrational Electrolyte Salts. # Diagram

SAFER ALTERNATIVES: Early and adequate intake of home based fluids (rice water, kanji water, sugar-salt solution, shikanji (lime juice with sugar and salt) herbal tea, saunf or ajwain water, jeera water, lassi, salted butter milk, tender

52.1Taste of Tears, VHAI, July 1984, p. 28.
52.2Ibid., p. 29.

coconut water, dilute dal water). UNICEF/ WHO recommended ORS, which are cheaper and should be made easily available.

The bottom line of course is that adequate safe drinking water should be made available to the people and this is the primary prevention against diarrhoea and dehydration. Methods of decontamination of water at home level must be made known and available e.g., boiling, putting water in transparent containers in the hot sun, use of chlorine, iodine drops. (# Diagram use of Chlorine)

53. FIXED DOSE COMBINATIONS OF PHENYLBUTAZONE OR OXYPHENBUTAZONE WITH ANY OTHER DRUG

REASON FOR BANNING: Can cause agranulocytosis[53.1] (a fatal blood disease), stomach ulcers, liver and kidney damage.

"....because of its toxicity (Phenylbutazone) is not employed as a general analgesic or antipyretic".[53.2]

"Phenylbutazone should be employed only after other drugs have failed, and then only after careful consideration of the risk involved as compared with the advantage to the patient".[53.3]

"Side-effects occur in 20-40 per cent of patients".[53.4]

Production and sale of Tanderil-Phenylbutazone has been withdrawn from the world market by Ciba Geigy.[53.5]

Oxyphenbutazone has been used by mouth in rheumatic disorders such as ankylosing spondyitis, Osteoarthritis, rheumatoid arthritis but such use is no longer considered justified owing to the risk of severe haematological adverse effects.[53.6]

USED: Mainly for inflammation, but also for pain and fever.

WHO Comment: Phenylbutazone, a pyrazolone derivative with anti-inflammatory, analgesic and antipyretic activity, was introduced in 1949 for the treatment of rheumatic disorders. Its use was subsequently associated with serious and sometimes fatal adverse reactions, notably cases of aplastic anaemia and agranulocytosis. Many national drug regulatory authorities consider that more recently introduced drugs offer a safer alternative for most, if not all, patients requiring anti-inflammatory agents. Phenylbutazone has thus been either withdrawn at the national level or retained with rigorously restricted indications for patients unresponsive to other therapy. These restrictions also apply, in general, to combination products containing phenylbutazone.[53.7]

Country banned: Belgium, Ghana, Sri Lanka, Armenia, Australia, Austria, Bahrain, Cyprus, United Kingdom, Israel.[53.8]

Brand	***Manufacturer***
SIORIL	ALBERT DAVID (OXYPHENBUTAZONE)

COUNTRIES WHERE BANNED:
1984 United Arab Emirates, Cyprus,

53.1 Agranulocytosis is a blood disease (often fatal) in which the bone marrow fails to produce white blood cells (which fight infection and are essential to life) so that patient easily succumbs to infection and can die.

Finland, Iceland, Tunisia, Jordan, Barbados, Zimbabwe, Spain, Bangladesh

1985 Netherlands, Sweden, New Zealand, Oman, Turkey, Austria, Chile Congo, Federal Republic of Germany, United Kingdom, Hungary, Israel, Japan, German Democratic Republic, Italy and Philippines have banned phenylbutazone but not oxyphenbutazone whereas Finland has not banned phenylbutazone.

SAFER ALTERNATIVES: For inflammation: aspirin or indomethacin, for pain, fever: aspirin or paracetamol.

54. FIXED DOSE COMBINATION OF ANALGIN WITH ANY OTHER DRUG OTHER THAN ANTI-SPASMODICS

There are many generic brands of analgin available in the form of tablets, injectable and syrup. Most of the analgin combinations now banned, will continue to use the same brand name by changing the formulation.

Due to the wording after ban, following are the single ingredient (analgin) brand products, which continue to be marketed.

Brand	***Manufacturer***
ANALGIN	ALKEM
BARALGAN-M	AVENTIS
NOVALGIN	AVENTIS

While 'analgin combinations' have been banned the antispasmodic analgin combinations and plain analgin is allowed.

REASONS FOR BANNING: Dipyrone, like Amidopyrine can cause agranulocytosis - a fatal blood disease. Safer, cheaper adequate substitutes are available.

"Administration of dipyrone is associated with an increased risk of agranulocytosis and with shock".

Pyrozolan derivative group of drugs includes phenylbutazone, oxyphenbutazone, antipyrine, aminiopyrine and dipyrone. These drugs have been in clinical use for many years, with the exception of antipyrine which is used in otic(ear) drops these preparations are not available in US, because of their propensity to cause irreversible agranulocytosis. Dipyrone was banned in the US, some European nations in the 1970s after reports of agranulocytosis among users. (However it continues to be used in several European, Asian and Latin American countries.

However it has been recommended that oral dipyrone only be used when other analgesics have failed (Arellano and Sacristan 1990).[54.1]

WHO Comment: Metamizole sodium, a pyrazolone derivative with analgestic, antipyretic and anti-inflammatory activity, was introduced in 1921 and has since been widely available in over the counter products. By the early 1970s its use had been associated, as with some other pyrazolones, with serious and sometimes fatal adverse reactions, notably cases of

53.2Martindale, The Extra Pharmacopoeia, 30th Edition, 1993, p. 29.
53.3Goodman & Gilman, The Pharmacological Basis of Therapeutics 8th Edition, 1991, p. 655.
53.4British National Formulary, 1983, p. 299 quoted.
53.5Ciba-Geigy: Press Release, April 1985.
53.6Martindale, The Extra Pharmacopoeia: 30th Edition, 1993, p. 27.
53.7UN Consolidated List, 8th Edition, 2003, p. 184.
53.8UN Consolidated List, 8th Edition, 2003, p. 184.

blood dyscrasias including agranulocytosis, which led to its withdrawal by some regulatory authorities (see full list). Although preparations of metamizole sodium are prohibited in certain countries, they remain widely available in others and, in some cases, in over-the-counter products.[54.2]

WHO comment: Pyrazolone derivatives, which include aminophenazone, metamizole sodium, phenylbutazone and propyphenazone have been associated with serious adverse effects. Since safer alternatives are widely available some regulatory authorities have withdrawn or severely restricted all pharmaceutical preparations containing pyrazolone derivatives. See also WHO comments for amiophenazone, metamizole sodium, phenylbutazone and propyphenazone.[54.3]

Scientific common name synonyms: analgin, Dipyrone, Dipyron, Methanesulfonic acid, methampyrone, Noramidopyrine, Methanesulfonate Sodium, Sulpyrine, Sulprin.

History of Banning

United States :	Banned on 27-06-1977 for human use. Stocks recalled. Banned in 1995 for feed animals. Stocks recalled. Many other countries have banned the use in animal feeds.
Germany :	The country of origin. Allowed only for severely limited i.e. Acute, moderate to severe pain secondary to tissue damage. Strictly prescription only drug.
Sweden :	Banned in 1974 even before USA. Reintroduced in 1995 for severely restricted indications for use in hospitals only. Again banned on 28-04-1999 because despite restricted hospital use, there were 7 cases of bone marrow depression.
Subcontinent:	Banned in Nepal and Bangladesh.
India :	Freely available without any prescription

Sales figures in India: Rs.19.25 for just one Company (Aventis) + other manufacturers + generic = Approx. Rs. 40 crores.

Countries where banned or restricted: Australia 1965, Norway 1976, Philippines 1977, USA 1977, Kuwait 1978, Italy 1979, Denmark 1979, Saudi Arabia 1980, Argentina 1981, Sudan 1982, Bangladesh 1982, Egypt 1983, Israel 1985, Belgium 1987, Malaysia 1987, Germany 1987, Pakistan 1988, Spain 1989, Netherlands 1990, Chile 1992, Sri Lanka 1992, Thailand 1994, Nepal 1997, Syria 1998, Yemen 1998, Zimbabwe 1998, Sweden 1999, Morocco 2000, Columbia 2000, Armenia, Bahrain, Great Britain, Ireland, Mexico, Peru.[54.4]

Brands available in the market.

Brands	***Manufacturer***
ANALGIN	ALKEM

54.1Goodman & Gilman, The Pharmacological Basic of Therapeutics, 10th Edition 2003, p. 714.
54.2UN Consolidated List, 8th Edition, 2003, p. 143

BARALGAN – M	AVENTIS
NOVALGIN	AVENTIS

55. FIXED DOSE COMBINATION OF DEXTROPROPOXYPHENE WITH ANY OTHER DRUG OTHER THAN ANTI-SPASMODICS AND/OR NSAIDS

There are a disturbing number of fatalities from either accidental or intentional overdosage with dextropropoxyphene. Many reports emphasise the rapidity with which it ensues. Death within an hour of overdosage is considered by some not to be uncommon. Overdosage is often complicated by patients also taking alcohol and using mixed preparations such as dextropropoxyphene with paracetamol or aspirin.
"Prolonged use of dextropropoxyphene hydrochloride may lead to dependence of the morphine type. It has been subject to abuse."[55.1]

Given alone, dextropropoxyphene is a very weak analgesic, and an important disadvantage when given with aspirin or paracetamol is that overdosage (which may be combined with alcohol) is complicated by respiratory depression and acute heart failure due to dextropróxyphene and by hepatotoxicity due to paracetamol.

Dextropropoxyphene is not mentioned in PDR 2.
Brands not available in the market.

56. FIXED DOSE COMBINATION OF A DRUG, STANDARDS OF WHICH ARE PRESCRIBED IN THE SECOND SCHEDULE TO THE SAID ACT WITH AN AYURVEDIC, SIDDHA OR UNANI DRUG

The fixed dose combination of a drug, standards of which are prescribed in second schedule to the said act — are not known to general public nor is the list of brand names affected by the above ban available at present. We hope that the Drug Controller of India will make the list of banned drugs available to the public in keeping with the direction of the Supreme Court.

There are no standards prescribed and many such brands are available in the market.

57. PARENTERAL PREPARATIONS CONTAINING FIXED DOSE COMBINATION OF STREPTOMYCIN WITH PENICILLIN (EFFECT FROM 01-01-1998 GSR NO 93E DATED 28.02.1997)

FIXED DOSE COMBINATIONS OF STREPTOMYCIN & PENICILLIN

REASONS FOR BANNING: Dangerous. Streptomycin is used to treat tuberculosis and should be reserved for this purpose only. If combined with other drugs which are not useful for treating tuberculosis. (like penicillin, the combination is used for purpose other than tuberculosis) resistance to streptomycin increases, making it useless for tuberculosis patients. Safer broad spectrum antibiotics are available which do not have this effect.

"Because of its toxicity and tendency to develop bacterial resistance, this drug

.54.3UN Consolidated List, 8th Edition, 2003, p. 276.

54.4UN Consolidated List, 8th Edition, 2003, p. 143.

should be reserved for treatment of tuberculosis and the few other serious disease for which it is clearly indicated".[57.1]

"When Intramuscular injections of streptomycin and penicillin were mixed both drugs lose about 30% of their potency within 30 minutes".[57.2]

"Use of Streptomycin in combination with penicillin even for bacterial endocarditis has not been mentioned by Oxford Text Book of Medicine".

The dose of Streptomycin in the available combinations is 500mg per dose which is definitely inadequate when it is to be used in subacute bacterial endocarditis.
"Streptomycin is a drug of choice in the treatment of tuberculosis and should generally be reserved for this use because when used in the treatment of other bacterial infections resistance has been found to develop within 2 to 3 days".

"Although such strains of **E-Coli** are highly resistant to streptomycin, they are not wide-spread in nature, similarly, only 5% of strains of 64 **Pseudomonas aeruginosa** exhibit such ribosomal resistance to streptomycin. However, up to 50% of strains of enterococci isolated from patients with endocarditis are resistant to high concentrations of streptomycin, and ribosomes from these strains fail to bind the antibiotic. For this reason there is no synergistic effect of penicillin and streptomycin against these strains demonstrable in vitro".

"Streptomycin is now rarely used except for the treatment of certain types of streptococeal bacterial endocarditis, tularemia, plague, and as a second-or 'third-line agent for tuberculosis".

Reason why Streptomycin Penicillin fixed dose combination should be banned.

Mixing penicillins with aminoglycosides in vitro has resulted in substantial mutual inactivation, if these groups of antibacterials are to be administered concurrently, they should be administered at separate sites at least one hour apart.

"Among the less common toxic reaction to streptomycin is peripheral neuritis. This may be due either to accidental injection of a nerve during the course of parenteral therapy or to toxicity involving nerves remote from the site of antibiotic administration".

"The administration of streptomycin in parenteral form should be reserved for patients where adequate laboratory and audiometric testing facilities are available during therapy" PDR 49th and 1995 p. 2100.

Streptomycin Penicillin combination is being used for several infections including Respiratory infections – this could mask the diagnosis of Tuberculosis this make Treatment more difficult.
Streptomycin: Is an aminoglycoside active against Mycobacterium tuberculosis and is now almost entirely reserved for tuberculosis. Streptomycin now rarely used in the UK except for resistant organisms.[57.3]

55.1Martindale: The Extra Pharmacopoeia, 30th Edition, 1993 p. 1071.
57.1Problem Drugs, HAI, 1995.
57.2Martindale, 28th Edition, 1985, p. 1213.
57.3 BNF No. 32, p. 256.

Penicillin and aminoglycosides must never be mixed in the same bottle because the penicillin inactivates the aminoglycosides to a significant degree.[57.4]

Widespread emergence of resistance has largely put paid to its use in infections due to common gram negative aerobes.[57.5]

Thus a combination of streptomycin and penicillin is not advisable.

Drugs containing streptomycin and penicillin in parenteral forms available in the market are as follows.

Brand	*Manufacturer*
Bistrepen	Alembic
Bistrepen Forte	Alembic
Bistrepen Paed	Alembic

58. MEPACRINE HYDROCHLORIDE (QUINACRINE AND ITS SALTS) IN ANY DOSAGE FORM FOR FEMALE STERILIZATION OR CONTRACEPTION

REASONS FOR BANNING: The drug was misused for female sterilisation, for details see section on Drugs misused in unethical clinical trials. The drug is anyway not a part of drug regime recommended for the National Malaria Eradication Programme as per NMEP guidelines.

Brands available.

Brand	*Manufacturer*
MALADIN (used for malaria)	UNICURE

57.4 Goodman & Gilman 7th Edition, 1985, p. 11621.
57.5 Martindale 30th Edition, 1993, p. 203.

59. PHENFLURAMINE AND DEXFENFLURAMINE

REASONS FOR BANNING: Phenfluramine usually depresses rather than stimulates the CNS. It has been associated with serious cardio vascular toxicity. Pulmonary hypertension led to certain precautions being imposed upon its use and subsequent reports of valvular heart defects led to its withdrawal worldwide.[59.1]

Brands not available in the market.

60/63. FIXED DOSE COMBINATION OF HAEMOGLOBIN IN ANY FORM (NATURAL OR SYNTHETIC); EFFECTIVE DATE SEPT. 1, 2000 NO. GSR 814(E)DT. 16-12-1999.

No Pharmacology book refers to use of haemoglobin in any form for oral use to replenish iron. As such, giving haemoglobin in any form is unjustifiable. There are no references to show that haemoglobin given orally raises haemoglobin or iron contents of the blood. The blood used for obtaining heam is from the slaughterhouses. It is very inappropriate and costly way of increasing haemoglobin. Many vegetarians would be offended if they were aware of what they were consuming specially for religious reasons. Sofar, cheaper, more effective alternative of Iron and Iron and folic acid exist and have been effectively used.

Brands still available in the market:

Brands	*Manufacturer*
BLO -SYN	REXCEL (RANBAXY)

GLOBAC	ZYDUS CADILA
GLOBAC –Z	ZYDUS CADILA
GLOBAC –Z	ZYDUS CADILA
SOFTULES	CADILA
HEAM UP GEMS :Plus	CADILLA
HEMEGA SYP	MEGACARE
HEMEGA TR	MEGA CARE
HEMFAST	SARABHAI
HEMFER	ALKEM
HEPP FORTE	LUPIN
PROBOFEX	WOCKHARDT
C HAEMOGLOBIN SYP	
UNIGLOBIN	UNIVERSAL

61/64: FIXED DOSE COMBINATION OF PANCREATIN OR PANCRELIPASE CONTAINING AMYLASE, PROTEASE AND LIPASE WITH ANY OTHER ENZYME

Pancreatin is inactivated by gastric acid and thus enteric coated preparations are ideal, giving it alongwith other enzymes does not serve the desired purpose and hence the fixed dose combination is superfluous.

Brands available in the market:

Brand	*Manufacturer*
DISPEPTAL	NICHOLAS PIRAMAL
ENZAR FORTE	ELDER
ENZYSTAL	TORRENT
FESTAL – N	AVENTIS
GESDYP	REXCEL
PANOLASE	UNICHEM
PANZYNORM	GERMAN REM
PAPYTAZYME	AFD
DIGIPLEX –T	SHREYA
FESTAL	AVENTIS[64.1]

62. FIXED DOSE COMBINATION OF VITAMIN B1, VITAMIN B6 AND VITAMIN B12 FOR HUMAN USE. EFFECTIVE DATE: JAN 1, 2001 NO.GSR 702 (E) DT 14-10-1999

REASONS FOR BANNING: Gross misuse and overuse of B1, B6 and B12 combination when they are easily available in food.

Deficiency of the B Vitamins is usually treated by preparations containing thiamine (B1) riboflavin (B2) and nicotinamide, which is used in preference to nicotinic acids as it does not cause vasodilatation. The severe deficiency states are best treated by the parental administration of B vitamins; anaphylaxis has been reported with these preparations.[62.1]

Vitamin B12 deficiency can result in irreversible damage to the nervous system. Therapy should always be as specific as possible. While a large number of multivitamin preparations are available, the use of 'shotgun' vitamin therapy in the treatment of vitamin B12 deficiency can be dangerous. With such therapy, there is danger that sufficient folic acid will not be given to result in a hematological recovery; however, this may mask continued vitamin B12 deficiency, and neurological damage will develop or progress if already present.[62.2]

Brands available in the market:[62.3]

ARISTONEUROL	ARISTO
BARAPLEX	AFD
BEVIDOX	PHARMACIA H CARE
EMBION	SYMBIOTIC
NAXIBION FORTE	DYNAMIC LABS
NEUROBION FORTE	MERCK
NEUROKEM	ALKEM
NEUROPLON –12	KHANDELWAL
NEUROXIN 12	ZYDUS CADILA
PYRIMINE 12	JAGSONPAL
SIONEURON	ALBERT DAVID

59.1 Martindale, 33rd Edition, 2003, p.1510-1.

STAMINE	STADMED
TRINEUROSOL	INDUS PHARMA
TRINEUROSOL – H	MERIND
VITNEURIN	GLAXO SMITHKLINE

63. PLEASE SEE 60/63 ABOVE

64. PLEASE SEE 61/64 ABOVE

65. FIXED DOSE COMBINATION OF DIAZEPAM AND DIPHENHYDRAMINE HYDROCHLORIDE

CSM Advise: Benzodiazepine are indicated for the short-term relief (two to four weeks only) of anxiety that is severe, disabling or subjecting the individual to unacceptable distress, occurring alone or in association with insomnia or short-term psychosomatic organic or psychotic illness. The use of benzodiazepines to treat short-term mild anxiety is inappropriate and unsuitable. Benzodiazepines should be used to treat insomnia only when it is severe, disabling, or subjecting the individual to extreme distress.[65.1]

Thus a combination of diazepam diphenhydramine hydrochloride is irrational and is likely to be habit forming. Brands available in the market:

Brand	***Manufacturer***
SEDYN	MM LABS

66. FIXED DOSE COMBINATION OF NITROFURANTOIN WITH TRIMETHOPRIM.

Trimethoprim has no synergistic action with nitrofurantoin and hence this fixed dose combination is superfluous. Increased chances of emergence of drug resistance when used as combination. Brands available in the market:

Brand	***Manufacturer***
TRIFURAN	M.M.LABS

67. FIXED DOSE COMBINATION OF PHENOBARBITONE WITH ANY ANTI-ASTHMATIC DRUGS

Barbiturates depress both the respiratory drive and the mechanisms responsible for the rhythmic character of respiration. The use of barbiturates as sedative hypnotic drugs is justifiably on the decline because they lack specificity of effect in CNS, they have a lower therapeutic index than do the benzodiazepines, tolerance occurs more frequently than with benzodiazepines, the liability for abuse is greater, and there is a considerable number of drug interactions.[67.1]

Precautions: Phenobarbitone and other barbiturates should be used with care in children and elderly patients, in those in acute pain, and those with mental depression. Also they should be given cautiously to patients with impaired hepatic, renal or respiratory functions and may be contra-indicated when the impairment is severe.[67.2]

Brands available in the market:

Brand	***Manufacturer***
ALERGIN	CIPLA
ASMAPAX DEPOT	NICHOLAS

64.1 Drug Today 44, Apr.-June 2004.

62.1 BNF No. 32 p. 399.

62.2 Goodman & Gilman 7th Edition, 1995, p. 1330.

62.3 Drug Today July-Sept 2003.

ASTHMINO	JAGSONPAL
ASTHOCAP	SAMSON
CADIPHYLATE ELIXIR	CADILA HEALTHCARE
CORTASHTHMA	CADILA-H
TEDRAL LIQUID	PARKE DAVIS
TEDRAL E	PARKE DAVIS
THEOCORTINDON	INDO PHARMA
THEOMAC	MAC

68. FIXED DOSE COMBINATION OF PHENOBARBITONE WITH HYOSCIN AND/ HYOSCYAMINE

No brands available in the market.

69. FIXED DOSE COMBINATION OF PHENOBARBITONE WITH ERGOTAMINE AND /OR BELLADONA

No brands available in the market.

70. FIXED DOSE COMBINATION OF HALOPERIDOL WITH ANY ANTI-CHOLINERGIC AGENT INCLUDING PROPENTHELINE BROMIDE

This combination has been grouped under the heading of "Antimanic Drugs" and Propentheline in that dose is not desired. Brands available in the market.

Brand	*Manufacturer*
SERE BANTHINE	RPG

71. FIXED DOSE COMBINATION OF NALIDIXIC ACID WITH ANY ANTI-AMOEBIC INCLUDING METRONIDAZOLE: EFFECTIVE DATE: JAN 1, 2002 NO.GSR 170 (E) DT 12.03.2001

Nalidixic acid is bactericidal to most of the common gram-negative bacteria that cause urinary tract infection.

The most frequent adverse reactions to nalidixic acid involve the gastro-intestinal tract, skin, and central nervous systems. Gastro-intestinal effects have been reported in about 8% of patients and include nausea, vomiting, diarrhoea, and abdominal pain. It should be avoided in babies less than 3 months old.

Since nalidixic acid and related antimicrobial agents have been shown to cause degenerative changes in weight-bearing joints of young animals, it has been suggested that these compounds should not be used in children, adolescents and pregnant women, during lactation.[71.1]

This combination has been grouped under the heading of anti-diarrhoeals and the dose suggested is 2 tabs (nalidixic acid 500mg + Metronidazole 200 mg) 3-4 times daily for 5-7 days. This is obviously a sub-standard dose for urinary tract infection and may develop resistance. When it is contraindicated for babies less than 3 months old we have suspensions and syrups available for children. This is certainly hazardous.

The recommended dose for adults is 1g four times a day for 1 to 2 weeks; thereafter a daily dose of 2 g is suggested. The drug should not be used in infants under 3 months of age.[71.2]
Brands available in the market.

65.1BNF No. 32 p. 151.
67.1Goodman & Gilman Edition 7th, 1985, p. 355.
67.2Martindale, 30th Edition, 1992, p. 302.

Brands	*Manufacturer*
ABDOGYL	GLAXO SMITHKLINE
ABICON	SHREYA
AD 500	AROBINDO PHARMA
ALDIAGRAM	ALKEM
BACTOMET	WIN MEDICARE
BACTOMET – C	WIN MEDICARE
BESCOTRIM SUSP	MAC LAB
BETADIX	AGRON
DARMED	COMED
ENTROZYME –M	STADMED
ENZOLE	MERCURY
GENOGYL –N	GENO
GRAMONEG –M	RANBAXY
GRAMONEX	NESTOR
GRAMONEX C	NESTOR
IZOL	DYNAMIC LAB
MEXIGYL	MEDICAMEN
NALIDYS	B E
NEGADIX M	CFL
QUGYL N	RPG
SPROT N	MAPRA
ULIX M	BLUE CROSS

72. FIXED DOSE COMBINATION OF LOPERAMIDE HYDROCHLORIDE WITH FURAZOLIDONE

Antimotility drugs have a very limited role as adjunct to fluid and electrolyte replacement, they are not recommended for acute diarrhoea in young children.[72.1] Furazolidone not mentioned in BNF.

Furazolidone: Involves the gastro-intestinal tract, nausea and vomiting, dizziness drowsiness, headache and general malaise have also been reported. Allergic reactions, most commonly skin reactions such as rashes or angioedema may occur. There have been instances of acute pulmonary reactions, similar to those seen with the structurally related drug nitrofurantoin, and is hepatotoxic. Agranulocytosis has been reported rarely. Haemolytic anaemia may occur in patients with a deficiency of glucose 6 phosphate dehydrogenase deficiency given furazolidone.[72.2]

Loperamide hydrochloride inhibits intestinal motility and is used in the management of acute and chronic diarrhoea. Adverse effects include toxic megacolon, dry mouth, dizziness, fatigue and hypersensitivity reactions. The main aim in treating acute diarrhoea is the correction of fluid and electrolyte depletion with rehydration therapy. In the US loperamide is not recommended in children under the age of 4 years.[72.3]

Furazolidine is a MAOI inhibitor and is used to treat giardiasis. It is hepatotoxic and can cause hemolytic anaemia in patients with G-6PD deficiency. Tyramine containing foods have to be avoided while on furazolidone therapy. As a member of the nitrofurans group of drugs, it is carcinogenic and mutagenic. It has been withdrawn and/or banned in most western countries, including Britain, Australia etc.[72.4] *As such combination of the two drugs is hazardous.*

Over dosage however can result in CNS depression and paralytic lieus Children may be more sensitive than adults to CNS depressant effects of loperamide. In patients with active inflammatory diseases of the colon.
Loperamide should be used with great caution, if at all to prevent development of toxic megacaion.[72.5]
Brands containing a combinations of loperamide and furazolidone.

71.1 Martindale 30th Edition, 1993, p. 184.

71.2 Goodman & Gilman 7th Edition, 1985, p.1110.

Brand	Manufacturer
IMOZOL	JOHNSON & JOHNSON
IMOSEC-F	JOHNSON AND JOHNSON
KLASSAK	PLETHICO
SANIDIS	PANJON PHARMA

WHO comment: Loperamide, an inhibitor of intestinal peristalsis, was introduced in 1975 for the treatment of acute and chronic diarrhoea. In many countries its use was discouraged in young children. In late 1989, treatment of infants in Pakistan was associated with 19 cases of paralytic ileum, 6 of which have been fatal. This has subsequently led the major manufacturer to withdraw all drop formulations of the drug worldwide as well as the lower dose syrup forms from countries where there is a programme for the control of diarrhoeal diseases. The WHO control of diarrhoeal diseases programme recommends that loperamide should not be used in children below five year of age.

Countries where banned: Libya 1990, Pakistan 1990, Oman 1990, Peru 1990, Indonesia 1990, Mexico 1990, France 1990, Nepal 1991, Philippines 1991, Korea 1991, Lebanon 1991, Turkey 1991 and Sri Lanka 1991.[72.6]

73. FIXED DOSE COMBINATION OF CYPROHEPTADINE WITH LYSINE OR PEPTONE

Effective date: January 1, 2002
Notification No. GSR 170(E) dt. 12.3.01

REASONS FOR BANNING: Grouped under sedative antihistamines and the side effect is drowsiness that may affect performance of skilled tasks.[73.1]

Side effects of cyproheptadine include drowsiness, dry mouth, and many other effects common to H1 blockers and increased growth in children have been observed the mechanism may involve interference with regulation of the secretion of growth hormone.[73.2]

In general cyproheptadine appears to have no major effect in promoting weight gain. The use of drugs should be secondary to long term nutritional and behavioral approaches.[73.3]

Warning: Children – overdosage of antihistamines particularly in Infants and children, may produce hallucination, central nervous system depression, convulsions and death. Antihistamines may diminish mental alertness; conversely, particularly, in the young child, may occasionally produce excitation.[73.4]

Brands available in India

Brand	Manufacturer
APETAMINE	TABLETS (IND)
APILYSIN	RAYMOND
APPET	FINECURE
APTY	CADEX LAB
CYDINE	CFL PHARMA
HEALTH CARE CYPRODIT	CUBIT HEALTH CARE
HELTH CARE CYP-L	ALBERT DAVID
CYPEE	COMED CHEMICALS
CYP – L	ALBERT DAVID
CYAPTIN	DUCKBILL
CYAPTIN C CALCIUM	SF
CYLIP	DOLPHIN
CYPROWAL	WALLACE
CYPON DROPS	GENO

72.1BNF, 32, p. 42.
72.2Martindale, 30th Edition, 1993, p. 514.
72.3Martindale 30th Edition, 1993, p. 888.
72.4MIMS 23, Sept. 2003, p. 28.

CYPON SYRUP	GENO
DIZEST	DWD
G-1	GLYCO REMEDIES
JUVEN	VASPAR (IND)
L-CYPRO	WALLACE
LECYP	EAST AFRICAN ®
LYCIP	BRAWN
LYCYP	OVERSEAS H.CARE
MYPON	BROOKS PHARMA
PRACTIN-EN	MERIND
PRO-APP	CURE QUICK
REBOOM	PHARMATECH
SERITOL	DEW DROPS LTD
SORBEX PLUS	EXCARE LAB
TRICOL	TRICOL COSMAS PHARMA
CYPRODINE-L	ALDOC PHARMA

Through the FDC is banned on 12-03-2001 and with effect from 01-01-2002, we find this entry in "New Entries" of Drug Today, Apr.-June 2004.

(Source: Drug Today (Jan-Mar 04) p.659-660).[73.5]

74. ASTEMIZOLE

Astemizone is used as a antiallergic drug for rhinitis and conjunctivitis. Better alternatives are available. Can cause ventricular arrhythmia including 'torsade de' pontes have occurred countries rarely with astemazole.

Janssen preparation of astemizole have now been withdrawn from the market in most countries because of the risk of adverse effects.[74.1]

Brands of ASTEMIZOLE

Brand	***Form***	***Manufacturer***
Acemiz	tab & syp	Lupin
Acipax	tab	WyethLederle
Alerzole	tab, syp	Themis
Astelong	tab, syp	Torrent
Histeese	tab, syp	Micronova
Minastem	tab	Glenmark
Stemiz	tab, suspension	Cadila H
Synmizol	tab	Synmedic Lab

Year and Countries where banned

1987	Norway	Refused Registration
1996	New Zealand	Restricted medicine
1997	Argentina	Warning to be given
1998	UK	Prescription only
1998	Philippines	Withdrawal by Company
1999	USA	Withdrawal by company
1999	South Africa	Withdrawn
1999	UAE	Banned Sales
1999	Mauritius	
1999	Brunei	Withdrawn by manufacturer
1999	Darusalaam	Withdrawn by manufacturer
1999	Tanzania	Banned
2000	Armenia	Withdrawn by manufacturer
2000	Singapore	Banned

WHO Comment: The first clinically interested histamine H-antagonists were introduced in the late forties and early fifties. Several histamine H-antagonists have a similar cardiac effect to that seen with astemizole and terfenadine. Serious cardiovascular adverse reactions have been reported when used concomitantly with imidazole antifungals and macrolide antibiotics. See also under terfenadine. Countries where banned or restricted: USA, South Africa, UAE, Mauritius, Brunei, Tanzania, Armenia and Singapore.[74.2]

72.5Goodman & Gilman, 10th Edition, p.1040.

72.6US Consolidate List, 8th Edition, 2003, p. 131.

73.1BNF No. 32.

73.2Goodman & Gilman, 7th Edition, p. 635.

73.3Martindale, 30th Edition (Kennedy SH, Goldblood DS; Drugs 1991; 41; 367-77).

73.4 PDR 49th Edition, p. 1609.

75. TERFENADINE

Two other second generation H1, antagonists that had been marketed previously as temizole. Terfenadine were found in rare cases to induce a potentially fatal arrhythmia tor sades de pointes when their metabolism was impaired such as by the liver disease of drugs that inhibit the 3A family of P450 enzymes (hepatic microsomal system).

This led to the withdrawal of terfenadine and astemizole from the market in 1998 and 1999.[75.1]

Antiallergic. It should be avoided in patients with cardiac or significant hepatic disease, with hypokalemia or other electrolyte imbalance or with known or suspected long 'qt' interval (in ECG).[75.2]

Brand	***Form***	***Manufacturer***
Daylert	Syp	Micro
Histafen	tab	Deys
Rhiter	tab, susp	Panacea
Tedin	tab, syp	Gufic
Terdane	tab syp	Intas
Terf	tab, susp.	Lupin
Terfax	tab	Kopran
Terfed	tab, syp	Cipla
Terostar	tab	Arvind
Tofrin	tab syp	Torrent
Trexyl	tab syp	Rextar
Zeter	tab	Zee lab
Zoter	tab, syp	Alidac

TERFENADINE WITH PSEUDOEPHEDRINE

Brand	***Manufacturer***
Terfed -D	Cipla
Trexydin	Ranbáxy

73.5 Drug Today (Jan-Mar 04) p. 659-660.

74.1 Martindale, 33rd Edition, 2002, p. 409-2.

Countries where banned or restricted or withdrawn:

Finland	restricted prescription
Japan	warning
Oman	Prohibited registration
France	
Japan	
Morocco	
UK	
Oman	
USA	
Mauritius	
France	
Thailand	
Saudi Arabia	
Singapore	

76. PHENFORMIN

REASON FOR BANNING: (MIMS India October 2001)

Phenformin was banned and discarded the world over some 30 years ago for (a) causing 2.5 times more cardiovascular mortality (b) leading to lactic acidosis with 50 to 70 per cent of affected patients dying (c) reducing cardiac output (d) impairing kidney function and a host of other complications such as pancreatitis and (e) introduction of far better, low cost alternative metformin, belonging to the same group with superior effect and far less side-effects.[76.1a]

Phenformin's Forgotten fatalities[76.1b]
No standard text book of pharmacology (such as Goodman & Gilman, 9th edition 1996) has a chapter on phenformin, no company of any country from Pakistan to

Peru, from Australia to America, from Indonesia to Ireland or for that matter from Ethiopia to Ecuador markets phenformin. (But as the saying goes there is always an exception. Believe it or not) India is probably the only country where this drug, discarded more than two decades ago as just being too dangerous for human consumption, is still sold, and sold in plenty. Currently an estimated 100,000 diabetics in India are believed to be consuming this potentially life threatening drug.

Phenformin, a member of the biguanide group of antidiabetics (the other being metformin) was synthesized and introduced in the United States market in 1957. It remained in use till 1970 when a large, randomized study on 1027 patients conducted by the University Group Diabetic Programme (UGDP) found that Patients treated for 5 to 8 years with phenformin had a rate of cardiovascular mortality approximately 2.5 times compared to those (diabetics) who were not on any drug".
This led to immediate suspension of treatment with phenformin in the UGPDs study. Follow-up studies suggested higher incidence of hypertension and heart rate increase in patients on phenformin.

Worse was to follow. It was soon discovered that lactic acidosis was by far the most serious toxic side effect of phenformin with 50 to 70% cases ending in death. It can develop at any time during therapy, even in the absence of predisposing risk factors. Therefore an overview of phenformin concluded that "phenformin is no longer indicated for diabetes or any other condition. There is no situation in which clinical benefit derived from phenformin outweighs the risk of therapy".

One of the many problems with phenformin is that there are a very large number of people (upto 9%) who are genetically unable to metabolize the drug with required speed with the result that mean plasma levels shoot up from 100ng/mL to 152mg/mL leading to high blood lactate levels. Once the blood lactate level reaches 5mmol/L threshold, clinical lactic acidosis sets in. Besides phenformin is known to reduce cardiac output and decrease liver blood flow.[76.2] This reduced hepatic clearance of lactate and further increases the risk of lactic acidosis. Furthermore, the drug has adverse effects on kidney functions. It reduces the glomerular filtration rate (GFR) and thus impairs the body's ability to get rid of an acid load increasing the risk of lactic acidosis. Some reports have associated the use of phenformin to development of acute pancreatitis.[76.3] If concurrently taken, alcohol markedly raises blood lactate level often beyond safety limits.
What do we do to improve survival if a patient develops lactic acidosis due to the use of phenformin? Not very much except for administration of insulin. Haemodialysis can remove lactate and ketones from the circulation but phenformin is poorly removed. No therapy has been consistently effective. Death from cardiovascular collapse is frequent within 72 hours of symptom onset. Many patients survive the initial insult of acidosis but succumb to complications including renal failure,

74.2 UN Consolidated List, 8th Edition, 2003.
75.1Goodman and Gilman, 10th Edition, 2003, p. 655.
75.2 Martindale 33rd Edition, 2002 p. 425-1.

myocardial infarction or shock.[76.4] When in use in the United States, phenformin-induced lactic acidosis accounted for 27% of deaths due to metabolic acidosis in diabetics.[76.5] Patients taking phenformin have a 10 to 20 times greater risk of lactic acidosis compared to metformin.[76.6]

Metformin and Phenformin were introduced in 1957 and widely used Phenformin was withdrawn in many countries during the 1970s because of an association with lactic acidosis.[76.7]

(Banned because of reports of occasional but sometimes fatal cases of lactic acidosis among diabetics getting Biguanides.)
Countries where banned, restricted or withdrawn:
Turkey, Canada, Norway, New Zealand, Singapore, Brazil, Denmark, Finland, Italy, Germany, France, Austria, Sweden, Thailand, USA, Cyprus, Ethiopia, Ireland, Yemen, UK, Hong Kong, Mauritius, Netherlands, Saudi Arabia, Venezuela

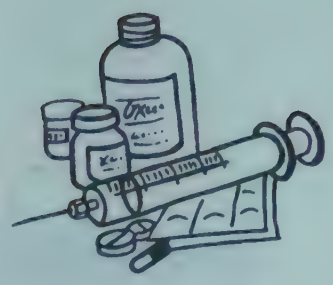
Ref: UN Consolidated List, p.176-177.[76.8]

"By 1976 clinical studies had conclusively demonstrated that hazards of Phenformin treatment outweighed the benefits".[76.9]

Brands of Phenformin available

Brand	***Content***	***Manufacturer***
Chlorformin	(Chlorpropamide Phenformin)	Cadila
DBI		USV
DBI-TD		USV

76.1aDr C.M. Gulhati, Editor, MIMS India, December 2000.
76.1bDr C.M. Gulhati, Editor, MIMS India, October 2001.
76.2 Gan et al 1992; Kwong & Brubacher 1998.
76.3 Wilmink & Frick, 1996; Dobrilla et al 1985.
76.4 McGuinness & Talbert, 1993.
76.5 NAMA Ap 1976.
76.6 Dr C.M. Gulhati, Editor, MIMS India, October 2000.
76.7 Goodman & Gilman @The Pharmaceological Basis of Therapeutics@, 10th Edition 2001, p. 1705.
76.8 UN Consolidated List, p. 176-177.
76.9 WHO Drug Information 2, 4, 1977 and UN Consolidated List.



6 Drugs Which Should be Banned or Severely Restricted

Countries which have never allowed these drugs, and therefore do not need to ban them are not listed here. Other countries (also not listed) have a legal structure which discourages the introduction of hazardous or irrational drugs.

1. ANABOLIC STEROIDS FOR CHILDREN

REASONS FOR BANNING: Dangerous

Stunts growth in children (prematurely stops long bones growing) and disturbs their sexual development (e.g. irreversible masculinisation of girls).

Their use as body-builders or tonics is quite unjustified".[1]

Large and repeated doses in early puberty may cause closure of the epiphyses and stop linear growth. Children may experience symptoms of virilization.[2]

"Serious disturbances of growth and of sexual and osseous development can occur when androgens are given to children".[3]

"Under the provisions of the Drugs (Control) Ordinance, low strength preparations were banned following unacceptable promotion encouraging their use in children suffering from malnutrition. The action in Bangladesh was taken having regard to inadmissible promotion of products containing anabolic steroids for malnourished children. These substances remain available at higher dosage in many countries, including Bangladesh, for several highly specific but limited indications that apply to selected patients with chronic debilitating and emaciating diseases, particularly associated with neoplasia and some types of aplastic anaemia".

USED: As a tonic and growth stimulant for children (unjustifiably), and as supportive treatment for rare disease such as aplastic anaemia and old age osteoporosis.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:
BANGLADESH

SAFER ALTERNATIVE: Nutritious food to maintain normal growth. Testosterone is used for aplastic anaemia and old age osteoporosis in men. Oestrogen is as effective as anabolic steroids for osteoporosis in women.

No brands available in the market.

Ref

1. *B.N.F. 1983, p. 237.*
2. *Martindale 30th Edition 1993, p. 1166.*
3. *Goodman & Gilman, 8th Edition 1991, p. 1420.*

2. FIXED DOSE COMBINATIONS OF CODEINE/ DEXTROMETHOR-PHAN/ NOSCAPINE/ LEVOPRO-OXYPHENE WITH EPHEDRINE AND/OR ANTIHISTAMINICS, FOR THE TREATMENT OF DRY COUGH

Codeine, dextromethorphan, noscapine and levopropoxyphene are habit forming substances.

Codeine, dextromethorphan and noscapine are derivatives of opium.

Codeine is a cough suppressant.

Ephedrine is a bronchodilator, it stimulates the respiratory centre, causes shrinking of mucous membrane, anxiety, restlessness, insomnia and can precipitate urinary retention in patients who have prostatic hypertrophy.

"Cough Suppressants are used too suppress irritant unproductive coughs but few have been shown to be effective by controlled clinical studies. The ideal cough suppressant should diminish the frequency and distress of coughing whilst not impairing reflex mechanisms allowing clearance of secretions. Their (dextro methorphan, noscapine, codeine, diamorphine, etc.) use in conditions characterised by the production of bronchial secretions, such as chronic bronchitis, or cystic fibrosis may result in sputum retention and the development of pneumonia".[1]

Ephedrine may increase the side effects of theophylline (gastrointestinal upset, insomnia, irritability and other CNS stimulant effects) without enhancing its efficacy. Probably it is best to avoid this combination.

COUGH EXPECTORANT

SIDE EFFECTS: Occasionally causes drowsiness, dizziness, excitation, mental confusion and gastrointestinal disturbances. Very high doses may produce respiratory depression.

PRECAUTIONS: Dextromethorphan should be administered with caution to patients with liver disease and to asthmatic patients.

Brand	*Manufacturer*
ALEX COUGH FORMULA	LYKA
CLISTIN	ETHNOR
CLISTIN – DMR	ETHNOR
COSOME	MERCK
DELETUS	NICHOLAS
ELTUSS	ELDER
GRILINCTUS	FRANCO INDIAN
HISTRAKOF	KOPRAN
LASTUSS LA	FDC
PEDIA 3	ETHNOR
PROTUSSA PLUS	BOOTS
RESPREN	ETHNOR
TRIOMINIC	WANDER
TRIATUSSIC	WANDER
TUSQ-P	BLUECROSS
ZEDEX	WOCKHARDT

LEVOPROPOXYPHENE

(1 Benzyl – 3 dimethylamino - 2 methyl – 1 phenylpropyl propionate naphthalene – 2 – sulphonate monohydrate cough suppressant). There are no Levopropoxyphene products in CIMS. No Levopropoxyphene in Pharmaceutical Index and in MIMS.

1. Martindale: The Extra Pharmacopoeia: 30th Edition 1993 p. 741.

Levopropoxyphene is a centrally acting cough suppresant, it has little or no analgesic activity.[1]

ANALGIN

"The risk of serious blood disorders in the presence of availability of safer alternatives do not justify its use".[2]

Dipyrone is the sodium sulphonate of Aminopyrine and has similar properties. Its use is justified only in serious or life threatening situations where no alternative antipyretic is available or suitable.

Dipyrone could aggravate haemorrhagic tendencies. Severe hypothermia might result if dipyrone and chlorpromazine were given concommitantly.

Dipyrone is likely to interact with food in the presence of gastric acid, which forms potentially carcinogenic N-Nitroso compounds, and particularly nitrous amines.[3]

The use of this drug and its combination had been banned, withdrawn or severely restricted. In June 1977, metamizol was withdrawn from the market and prohibited from export by the Food and Drug Administration of USA on the basis of reports of agranulocytosis, a sometimes fatal blood condition, associated with its use. The Director of the Bureau of Drugs found that agranulocytosis cannot be effectively prevented by frequent examination of treated patients since this condition can occur within a few hours following administration of the drug to a sensitive individual. In its decision the FDA cited the availability of effective orally administered drug products such as aspirin and acetaminophen and concluded that the risks associated with this drug far outweigh any benefit derived from its use, including use in Hodgkin's disease and similar malignant diseases of terminal nature.

The hearing of the German Federal Health Office finally confirmed the assumption of 1981 that one out of 30,000 to 60,000 patients will be affected with agranulocytosis caused by dipyrone. The German Federal Government found that the incidence of agranulocytosis was 24 times as high in users as in non-users. It has severely restricted all other indications excepting rare pain. Besides agranulocytosis and shock, there are other severe adverse reactions like Lyell's Syndrome (scalded skin) and other immune allergic reactions caused by dipyrone.

Another argument of spasmolytic activity of dipyrone injectible is propounded. Upto now there is no scientific proof of any spasmolytic (anti-spasmodic) effect of dipyrone, in therapeutic doses. It is clear that Hoechst does not believe in its own claim of spasmolytic activity, because Hoechst's own antispasmodic combination (Baralgan, Buscopan comp etc.) incorporates separate spasmolytic agents.[3]

Baralgan made by Hoechst which they recommend for use in Urolithiasis (Kidney Stone). Biliary disorders, Dysmenorrhoea (uterine pain during menstruation)

1. *Martindale 30th Edition, 1993, p. 749.*
2. *Problem Drugs – IOUC –1993.*
3. *Metamizol, kommentar Zu Barichten 4 eber labensbedrohiliche, Deutsches Arzteblatt 10-12-87 p. 2408-2411.*

contains: Analgin 500 mg. Pitofenone Hcl 5 mg. fenpiverinium Bromide 0.1 mg.

Central Pharmaceutical Affairs Council in Japan recommended that because of pyrazolone's (derivatives: amidopyrine, dipyrone, mofebutazone, nifenazone, oxyphenbutazone, phenazone, phenylbutazone) propensity to cause frequent skin eruptions (permanent disfiguring lesions including toxic epidermal necrolysis, exfoliative dermatitis, and Stevens Johnson's Syndrome) pyrazolones should no longer be included in proprietory cold medicines or in antipyretic-analgesic preparation available without doctors' prescription.

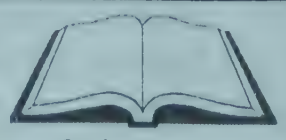
COUNTRIES WHERE BANNED OR RESTRICTED: Australia, Belgium, Chile, Denmark, Finland, France, Greece, Egypt, Israel, Italy, Japan, Korea, Mexico, Nepal, Norway, Peru, Philippines, Saudi Arabia, Singapore, Sweden, Turkey, USA, Venezuela, West Germany, Yemen, It is not available in UK.

"Analgin combinations" have been banned by German Drug Control Authorities and following that, by Pakistan. Analgin combinations have been recommended for being weeded out by our own Drug Technical Advisory Committee in 1987.

Analgin does not appear in the most recent reference textbooks such as Remington's Pharmaceutical Sciences (1986), Goodman and Gilman (1985). Drug, Facts and Comparisons (1985), Drugs Pharmacology Administration. Toxicity Nurses Reference Library (1985), Physicians Desk Reference, US.

4. Buko Pharma Campaign, Hoechst A Cause of illness, The Pharma Business in the Third World 1986, p. 19.

THE BOSTON STUDY



To prevent a worldwide ban of dipyrone, Hoechst started the so-called 'Boston Study' (IAAS, International Agranulocytosis Aplastic Anaemia Study).

The study was published in JAMA in October 1986.

Based on the result of the Boston Study, Hoechst started making claims of the 'risk estimate' of 1 case of agranulocytosis in every 1,000,000 patients. This has been questioned not only by well-known experts but also by the German Federal Health Office. German Federal Health Office has estimated the risk to be much higher and in its order dated 1.11.86 on dipyrone has said. "The decision of the IAAS does not allow to quantify the absolute risk".

German Drug Controllers explicitly say that "Due to its design Boston Study was not appropriate for supplying data on absolute risks". Boston Study was designed only to study agranulocytosis, but the major side effect of dipyrone is shock and cardiovascular reaction. These reactions are much more often reported than agranulocytosis. The Boston Study did not deal with this risk. The risk of a shock seems to be substantially higher than that of agranulocytosis. Risk of shock was estimated by Prof. Hackenthal (University of Heidelberg) to be of the order of 1 in 50,000 after oral intake and 1 in 5,000 after injection. Less severe hypotension due to shock can be seen even in 1 in 100 patients.

Dipyrone–What are the Alternatives

The "Arznel-Telegramm", a critical information service for physicians and pharmacists in the Federal Republic of Germany, examined possible substitutes for dipyrone and found that dipyrone can be replaced for all indications by better tolerated or more appropriate analgesics.

Fever

- Acetyl – salicyclic acid (ASA): 0.5 – lg.
- Paracetamol (Acetaminophen): 0.5 –lg.
- Ibuprofen 200 mg – 400 mg.

For children less than 15 years paracetamol is the drug of first choice. Children with otherwise harmless viral infections may develop Reye's Syndrome (liver necrosis with encephalopathy) after intake of ASA. Drug treatment has to be supported by physical measures such as wet compresses around the lower legs. Studies proving the superiority of dipyrone in the treatment of fever are inadequate, so that this widely held notion seems to be unfounded.

Dysmenorrhoea

* Ibuprofen * Pentazocin
* Naproxen * Dextropropoxyphene
*Other non-steroid anti-inflammatory drugs(NSAIDS)

Prostaglandin-synthesis-inhibitors such as ibuprofen and naproxen are a logical and effective principle of treatment, because painful abdominal cramps is caused by certain metabolites of the arachidonic and (prostaglandin). Non-steroidal anti-inflammatory agents are, therefore, superior to common analgesics.

Billary Colic

* Pethidine
* Pentazocin
* Morphine plus isosorbide dinitrate (ISDN)

The combination of morphine parenteral with ISDN is necessary in order to compensate for the spasmogenic effect of morphine to the unstriated muscles of the bililary tract and the intestine. The efficacy of ISDN is better than that of spasmogenics. If necessary, treatment can be continued with morphine oral and ISDN. Instead of morphine, other opiate can be taken.

Renal Colic

*As for biliary colic, additionally diclofenac, 75 mg. intramuscular (i.m.)

In a comparative analysis, diclofenac 75 mg. i.m. proved to be more effective than pethidine 100 mg. i.m. Further studies confirmed this pain-killing effect for biliary colics too.

Post-Operative and Post-traumatic Pain

* Morphine
* Buprenorphine
* Other Opiates

Since at least during the first few days after an operation or trauma, pain is severe and continuous, pain-relieving treatment should be carried out according to the clock (such as morphine every four hours, buprenorphine every six to eight hours. Dosage intervals vary according to the duration of effect of the opiate used. Non-steroid anti-inflammatory agents or anti-phlogistics are contra-indicated for subsidence and pain-relief due to the risk of renal insufficiency and should not be used before the fifth day post-traumatically and only in case of normal renal function.

Tumour Pain

* Morphine
* Other opiates

There are a number of therapeutic regimens, based on the duration of effect of the drug in order to find the necessary analgesic dosage and to apply the drug according to the clock. For the retarded morphine, the duration of effect seems to be eight hours, just like for buprenorphine. The analgesic effect of pentazocine is limited so that a frequent dosage is required. When opiates are used for long time they cause spastic constipation which can be treated with laxatives.

Other Severe Pain

Paracetamol (Acetaminophen 0.5 – lg. plus codeine (50-100 mg).

When an analgesic such as acetyl-salicylic acid (ASA) or paracetamol alone is not sufficient, the analgesic effect can be increased by an effective dosage of codeine (at least 50 mg). The effect of duration is – for both substances – five to six hours so

that a pain-relieving treatment is possible, by an administration every four hours.

Myocardial infarction: Clinical Management: General measures: pain relief:

Rapid and effective analgesia is the main requirement of most patients in the early stages of myocardial infarction. The opiates, morphine, and diamorphine are most effective for this purpose.When given by slow intravenous injection, either morphine, 10-15 mg, or diamorphine 5-10 mg, result in rapid pain relief. The emetic effect of both drugs result in unwanted circulatory stresses but may be lessened by the routine intravenous cyclizine 50 mg. Among alternative drugs are pethidine, methadone, and pentazocine. Pentazocine has been a source of some concern because a rise in pulmonary artery pressure following its administration has been observed in several studies. This finding has been associated with an elevation of left ventricular end-diastolic pressure in one study, suggesting a negative inotropic effect on the left ventricle. This has not, however, been a uniform observation and a direct effect on pulmonary arterioles has also been postulated. In any event, pentazocine, although an effective analgesic in doses of 30-60 mg intravenously, is probably best avoided because of its tendency to produce hallucinations... Some patients require a second or third dose of analgesic during the first 24-48 hours of admission, others are particularly anxious and benefit from sedation with a benzodiazepine, e.g. diazepam 2 – 5 mg thrice daily.... When potent analgesics may not be available; a period of prolonged pain and distress can be avoided by the use of a 50 per cent nitrous oxide/oxygen mixture, which can also be used during transport to hospital. The analgesic effects are rapidly reversed, which allows the patient to provide a history free from sedative effects of analgesia.[1]

Hyoscine butylbromide is a quaternary ammonium anti cholinergic agent. The peripheral effects of which are similar to those of atropine, but weaker and of shorter duration. Hyoscine butylbromide is used in the treatment of conditions associated with gastro-intestinal spasm. The usual dose is 20 mg intramuscularly or intravenously, repeated after 30 minutes if necessary. It is also given by mouth in doses of 20 mg four times daily, and is claimed to be of value in spasmodic dysmenorrhoea.[2]

Dicyclomine hydrochloride is an anticholinergic agent with peripheral effect similar to but much weaker than those of atropine, it also has direct antispasmodic action and a local anaesthetic action. It is used in biliary, gastrointestinal or urinary tract spasm and is given with antacids in the treatment of gastric and duodenal ulcer.[3]

Dicyclomine is indicated in functional bowel/irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. It is contra-indicated in obstructive uropathy (for example bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the

gastro-intestinal tract (as in achalasia, pyloroduodenal stenosis), paralytic lieus, intestinal atony of the elderly or debilitated patients, unstable cardio-vascular status in acute haemorrhage; severe ulcerative colitis, toxic megacolon/complicating ulcerative colitis, myasthenia gravis.[4]

Phenazopyridine hydrochloride: Symptomatic relief of pains, burning, frequency, urgency, and other discomforts arising from irritation of the lower urinary tract mucosa....Its topical analgesic action may reduce or eliminate the need of systemic analgesics or narcotics. Contra-indicated in renal insufficiency. A yellowish tinge of the skin, or sclerae may indicate accumulation due to impaired renal excretion and the need to discontinue therapy.[5]

Dextropropoxyphene hydrochloride (Propoxyphene hydrochloride) is a centrally acting narcotic analgesic agent. It is structurally related to methadone. The potency of propoxyphene hydrochloride is from two-thirds to equal that of codeine... Do not prescribe propoxyphene for patients who are suicidal or accident-prone. Prescribe propoxyphene with caution for patients taking tranquillisers or anti-depressant drugs and patients who use alcohol in excess. Tell your patients not to exceed the recommended dose and to limit their intake of alcohol.[1]

Prolonged use of higher doses of dextropropoxyphene may lead to dependence of the morphine type. Liability to abuse is reported to be a little less than for codeine side effect.

Pentazocin is a potent analgesic, which when administered orally is approximately equivalent, on a mg for mg basis, in analgesic effect to morphine. The respiratory depressant effects of pentazocin and its potential for elevating cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury.

For the relief of moderate to severe pain, 30 mg of pentazocin intramuscularly is reported to be equivalent to about 90-100 mg pentazocin by mouth, about 10 mg of morphine subcutaneously or intramuscularly. Pentazocin 66 mg intravenously appeared to be a suitable analgesic for patients with a recent myocardial infraction... Unlike morphine, its use was not generally followed by hypotension, an increase in the respiratory dead-space/tidal volume ratio or an increase in the difference between alveolar and arterial oxygen tensions...It was suggested that pentazocin should be used in preference to morphine as an analgesic in patients with myocardial infarction.

The results suggested that dimorphine might be considered to be the analgesic of choice in a situation where rapid relief of pain was essential but pentazocin with its low addiction potential and lower incidence of blood pressure reduction might be the most suitable treatment of pain in patients with a suspected cardiac infraction.

1. Oxford Text Book of Medicine: 1987: 21.27.
2. Oxford Text Book of Medicine: 1987: 12.202.
3. Oxford Text Book of Medicine: 1987: 13.172.
4. Martindale, The Extra Pharmacopoeia 30th Edition ,1993, p. 423.
5. Martindale, The Extra Pharmacopoeia 30th Edition, 1993, p. 29.

1. Goodman & Gilman 8th Edition, 1991, p. 510.

Drugs available in India

Buprenorphin hcl 0.3 mg/ml
- Addnok (Rusan Health Care)
- Bunogesic (Rusan Health Care)
- Buprinor (Astra Zeneca)
- Norphin (Unichem)
- Pentorel (Khandelwal)
- Tidigesic (Sun)

Carbamazepine 100, 200, 400 mg
- Carbatol (Torrent)
- Mazetol (SPPL)
- Tegrital (Novartis)
- Zeptol (Sun Pharma)

Dicyclomine Hcl 20 mg tab
- Bruspasm (Brooks Pharma)
- Dicmol (Pfiscar)
- Parvodex (Jagsonpal)

There are many FDCs of dextropropoxyphane with paracetamol, nimesulide, diclofenac, mefenamic acid, ravitidine, dextropripoxyphens and ethylnorphine.

Dextropropoxyphene available only in combination form with other analgesics like aspirin, paracetamol

Flavoxate Hcl
Flavate (Overseas Health Care)
Flavoxate (Elder)
Urispas (Walter Bushnel)
Urisol (Stadmed)

Hyoscine-N-Butyl Brom. 10 mg
Tab and 20 mg/ml inj.
- Buscopan (German Remedies)
- Belladenal – In (Novartis)
- Buscomol (Indus)

Pentazocin 30 mg/ml injection and 25 mg tablet
- Dolowin (Brown and Burke)
- Fortwin (Ranbaxy)
- Pentawin (Biochem)
- Susevin (Indoco)
- Wintal (Indus)

Phenazopyridine Hcl 100 mg tab
- Nephrogesic (Johnson & Johnson)
- Pyridium (Parke Davis))

Conclusion: Dipyrone (NOVALGIN, BARALGAN etc.) can be replaced by better-tolerated or more appropriate analgesics in all fields of indication. In many industrialized countries with a similar health care system, dipyrone has been banned, without any restrictions of therapeutical possibilities in the care of patients and where it is not banned, it's use is severely curtailed and used only in terminal cases.

HYDROXYQUINOLINES (Clioquinols)

Brand	*Manufacturer*
ANTIGYL COMP.	PHARMASYNTH
DEQUINOL	DEY'S
DIDOQUIN	RPG
ENTEROQUINOL	EAST INDIA
QUINOFORN	ALBERT DAVID

REASON FOR BANNING: Dangerous. Causes SMON[1] a painful nerve disease which causes limb paralysis, blindness and lack of bladder control. Effective and safer anti-amoebic drugs are available.
"Clioquinol has caused thousands of cases of SMON in Japan and elsewhere. A condition involving continuous pain, paralysis, blindness and, in extreme cases, death."[2]

"There is no convincing evidence to suggest that Clioquinol (is) effective in the prophylaxis of travellers' diarrhoea".[3]

"Hydroxyquinolines are active only on organisms present within the intestinal lumen. Used alone, therefore, they are active only in the absence of significant tissue invasion – a development that cannot be excluded with certainty even in patterns with asymptomatic amoebiasis".[4] Diodohydroxyquin and iodochloro-hydroxyquin have widely and all too often been indiscriminately employed for the treatment of diarrhoea. The use of these drugs, particularly at high doses for prolonged periods is unfortunately associated with significant risk. Administration of diodohyrdoxyquin in high doses to children with chronic diarrhoea, for example, has been associated with optic atrophy permanent loss of vision.[1]

Broxyquinoline has exactly the same properties concerning toxicities and there are cases in Sweden with exactly the same clinical picture as the clioquinol cases. So there is nothing to say that there are any differences in the toxicity of the different halogenated oxyquinolines.[2]

Antimicrobial drugs are not indicated for the routine treatment of acute diarrhoea. Their indiscriminate use must be discouraged not only because they are often of no value, but they are needlessly expensive and can also be harmful.

It was suggested that the Japanese epidemic might be due to genetic susceptibility but a few similar cases of SMON have been reported from several other countries in association with clioquinol or related hydroxyquinoline derivatives, such as broxyquinoline or di-iodohydroxyquinolne. Oral preparations of clioquinol have now been banned in most countries.[3]

USED: For diarrhoea and amoebic dysentry.

PAROXETINE

Paroxetine is an anti depressant. There have been recent spurt of reports regarding suicidal tendency in paediatric patients being treated with anti depressant medication particularly paroxetine.

According to the Drug Controller General of India – this drug is to be sold ONLY on prescription of a psychiatrist and used with caution.

The possibility of suicide attempt is inherent in major depressing disorders and may persist until significant remission occurs. Close supervision of high risk patients must accompany initial drug therapy. Prescription for paroxetine should be written for minimum necessary quantities in order to reduce the risk of overdose. Patients must be advised not to

1. *SMON: (Sub-Acute Myelo-optic Neuropathy): See note on late Dr. Olle Hansson.*
2. *Social Audit, Bad Information Means Bad Medicine, 1982.*
3. *British National Formulary, 1999 p. 50.'*
4. *WHO: Drug Information, January-March, 1978, PDT/D/781- see p. 55 for details.*

1. *Goodman & Gilman, The Pharmacological Basis of Therapeutics, 8th Edition, 1991 p. 1002.*
2. *Dr. Olle Hansson, Geneva Press Conference on SMON Proceedings: April 28, 1988, Geneva, p. 25.*
3. *Martindale: Extra Pharmacopoeia 30th Edition 1993 p. 511.*

discontinue use of any of these drugs without first consulting their physician.

Source: Communication from Shri Ashwini Kumar, Drug Controller General of India to Dr Abraham.

GalxoSmithKline Inc. (GSK), following discussions with Health Canada, would like to inform you of important safety information regarding the possibility that selective serotonin reuptake inhibitors (SSRIs) and other newer anti-depressants may be associated with behavioural and emotional changes, including risk of self-harm.

Brands	*Manufacturer*
PANEX	SYNAPSE (MICRO LABS)
PARI	INNOVA (IPCA)
PAROTIN	CIPLA (PROTEC)
RAXIT	SOLUS
XET	ZYDUS

Health Canada endorsed Important safety information on PAXIL (PAROXETINE)

Potential association with the occurrence of behavioural and emotional changes, including self-Harm.
Pediatrics: Placebo-Controlled Clinical Trial Data

Recent analyses of placebo-controlled clinical trial safety databases from SSRIs and other newer anti-depressants suggest that use of these drugs in patients under the age of 18 may be associated with behavioural and emotional changes, including an increased risk of suicidal ideation and behaviour over that of placebo.

The small denominators in the clinical trial database, as well as the variability in placebo rates, preclude reliable conclusions on the relative safety profiles among these drugs.

Adult and Pediatrics: Additional Data

There are clinical trial and post-marketing reports with SSRIs and other newer anti-depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment.

Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes.

Discontinuation Symptoms

Patients currently taking paroxetine should NOT be discontinued abruptly, due to risk of discontinuation symptoms. At the time that a medical decision is made to discontinue an SSRI or other newer anti-depressant drug, a gradual reduction in the dose rather than an abrupt cessation is recommended.

Paroxetine is not indicated for use in the pediatric population, and controlled clinical studies with paroxetine in children and adolescents under 18 years of age with major depressive disorder failed to demonstrate efficacy.

Source: Therapeutic Product Directorate : TDP-Web Glaxo SmithKline, May 2004
Health Canada Endorsed important safety information on paxil / paroxetine. Warning for SSRI's and other newer antidepressants.

DRUGS TO BE SEVERELY RESTRICTED

CISAPRIDE

Scientific and common name & Synonyms
Cisapridum.
Ireland Reports of cardiac arrhythmia, cardiac arrest and sudden death.[1]

Countries where banned and restricted
Ireland 1999
Philippines 2000
Oman2000
USA 2000
Argentina 2000
Columbia 2000
Germany 2000
Great Britain 2000
Muscat 2000
Canada 2000
Brunei 2000
Japan 2000
Armenia
New Zealand

Cisapride has been voluntarily withdrawn from the market because of the risk of rare but serious cardiac events associated with the drug. These include heart rhythm disorder and deaths associated mostly with the use of drug in people who are either taking certain other medications or who have certain underlying conditions that are known as risk factors.[2]

Philippines Banned the use of cisapride because documented reports on adverse events including deaths associated with its use.[3]

Oman suspended the marketing of Cisapride because of the possibility of rare but serious heart complications including arrhythmia and sudden death.[4]

UAE - indications for use of cisapride have been severely restricted because of the risk of rare but serious cardiac events associated with the drug.[5]
Ireland Reports of cardiac arrhythmia, cardiac arrest and sudden death.[6]

Cisapride

Brand	*Manufacturer*
BIPRIDE – MPS	CHEMO BIOLOGICAL
CESAP – MPS	DYNAMIC
CIPID & CIPID MPS	SHINTO
CISADE & CISADE MPS	UNICHEM
CISAGUT	BUPA PHARMA
CISA MPS	DYNAMIC
CISAPID & CISAPID MPS	KOPRAN
CISANORM	GUFIC
CISAPRO	CADILA H
CISAWAL	WALLACE
CISPEL	PANACEA
CISZY	ZEE LAB
CIZA, CIZA-20 & CIZA MPS	INTAS
CIZAP & CIZAP MPS	RELIANCE PHARMA
ESORID & ESORID MPS	SUN PHARMA
EZA MPS	PURE HEALTH
KEMOPRIDE & KEMOPRIDE MPS	CHEMO DRUGS
MOTEN	SOLUS
MOTICARE & MOTICARE MPS	INFAR
MOTILAX & MOTILAX MPS	USV
NORMAGUT	WOCKHARDT
NORMOKIME	WANDER
NUPRIDE	EAST INDIA
ONAPRIDE	SAYONA MEDICARE
ORTICID	ORTIN LAB
PERISTAL	MARC LAB
PERISTIL	DR REDDY'S LAB
PREPULSID	JOHNSON & JOHNSON

1. *IRDDS Drug Safety Newsletter, Sept. 1999.*
2. *EDA WWW.www.Fda.gov/med Watch/safety/200/ profile/hfm.*
3. *PHADO Administrative order (97) 2000, 09 Aug 2000.*
4. *OMNCR Circular No. 28/2000, 30 April 2000.*
5. *UAECW Communication to WHO 10 July 2000 and UN Consolidated List, 8th Edition, 2003, p. 59.*
6. *IRDDS Drug Safety Newsletter, Sept. 1999.*

PROCISA	JENBURKT
PROGIT	BAL PHARMA
PROKINE & PROKINE MPS	RPG
PRYDE	AUROBINDO PHARMA
RHONEPRIDE	NICHOLAS
RICHIPRIDE MPS	RICHIE
SANTIZA	LE SANTE
SYSPRIDE MPS	SYSTOPIC
ULCIPRIDE & ULCIPRIDE MPS	DAGON PHARMA
UNIPRIDE	TORRENT

MIFEPRISTONE (ABORTION PILL)

Mifepristone also known as RU486 is an abortificent. It is freely available over the counter. According to Dr S.G. Kabra, Petitioner in a PIL in the Rajasthan High Court, this drug is to be sold only on prescription of a registered obstetrician or gynecologist for use in the hospital or a recognised centre where facility for blood transfusion is available for therapeutic termination of intrauterine pregnancy.

Dr. Kabra has argued that according to the Year Book of family welfare India over 4 lakh registered abortions are done, with over 40,000 in Rajasthan alone.

Illegal abortions exceed legal abortions. The ratio being 8-10 illegal for one legal abortion. No. of induced abortions conducted are estimated to be 50-60 lakhs per year.

Complications such as failure peritonitis, septicaemica including death are known to occur.

In France where the drug was first introduced, 4 visits are required to a trained medical personnel in a registered medical centre (i.e. 4 trips to the hospital are required). On Ist visit ultrasound is done to confirm that duration of pregnancy is less than 7 weeks, 2nd to administer RU486, 3rd to confirm that abortion has taken place, if not prostaglandin injection is administered. 4th visit is to undertake gynecological exam to confirm that abortion has taken place completely. (It takes place 10 days later). The drug is not sold over the counter. Abortion takes place in a registered centre by trained personnel. In India it is sold over the counter, without warning and without follow up instructions. It is considered 91% effective if used appropriately. In selected persons in pregnancy less than 7 weeks. The consequences of an incomplete abortion for women, who are very anaemic, in a scenario where health facilities are unavailable or unaffordable would be disastrous.

Infact, loss of life has been reported with use of these drugs, as so many women don't know their proper use fully, and quacks or uninformed doctors who prescribe them, do not clarify that the drug should be used within 7 weeks of pregnancy i.e. within 2-3 weeks of the missed period.

Repeated doses taken after a longer gestation period do not help. There is concern about the impact of the drug on the foetus in case of continued pregnancy.

The Rajasthan State Human Rights Commission on hearing case no. 03/17/260 on March 2004 filed by Dr. S.G. Kabra

recommended that:

- The State government should ensure that free sale of mifepristone preparations from drugs stores, as prescription of 'Any' registered medical practitioner be stopped, as it is not only contrary to mandatory stipulations imposed by the Drug Controller of India, it is also wholly in violation of the provisions of MTP Act and the rules made there under.
- State Drugs Controller be directed by the State Government to ensure by proper surveillance through Drug Inspectors that, mifepristone and misoprostal are dispensed only on prescription of the doctors approved for MTP, who are attached to centres approved for MTP by the Director of Health Services, so as to ensure that these drugs namely mifepristone and misoprostal are supplied only to the approved MTP centres, and is not sold over the counter.
- Those including manufacturers medical practitioners and retailers who are found to be acting in violation of the drug and cosmetic act or the MTP Act should be prosecuted by initiating appropriate criminal action against them.

Misoprostal is a prostaglandin.

RU486 abortion pills were invented by Dr. Elienne Emile Baulice in 1992 who saw it as achieving two goals "helping women preserve health" and "humanity addressing demographic crisis". RU486 derived its name from the initials of its manufacturer, Roussel Uclaf. It is also known as the French "abortion pill".

RU486 is a chemical abortificient used since 1988 in France to terminate early pregnancy (i.e. upto 7 weeks). Its generic name is mifepristone (brand name mifegynae).

It is an effective progesterone antagonist administered as a tablet, in conjunction with a small dose of a prostaglandin, which increases the frequency and length of the uterine contractions needed to expel an embryo.[7]

Mode of Action

Prevention of implantation of the developing embryo in the uterus or dislodging it from the uterine wall after implantation.

According to Klien[7.1] et al 1992 pg. 57 the drug affects other sites also but little research exists.

Women in Netherlands, Europe prefer termination by vacuum aspiration.

Research indicates that abortion performed with the use of RU486 and prostaglandin is harsher for women than good, compassionately conducted abortion under local anesthesia under proper care.

The adverse effects are bleeding and

pain. Bleeding has been significant so as to warrant blood transfusion. (5 transfusions in 580 women and many emergency curettages in UK study (Klein 1992) have been reported.

Access to blood is not easy and there is hesitation among many male members to donate blood for their wives due to discrimination and because they are afraid of developing "weakness, as many believe that 100 drops of blood is equal to one drop of semen". Increased risk of uterine infection and perforation alongwith anesthesia complications are other potential hazards.
It is not cheaper either.
Efficacy of abortion pill depends on its correct usage, right dosage, with administration of prostaglandin at the appropriate time and for right indication i.e. termination of pregnancy less than 7 weeks. Women die of unsafe abortions in developing countries because of uncontrolled bleeding and infection.

A large number of women seek abortion at a later stage of pregnancy due to many reasons:

- Lack of awareness about their rights to get on abortion
- Lack of confidentiality
- Ignorance about abortion facilities
- Lack of resources and means of transport etc.
- Lack of safe abortion services
- 'internalised abortion shame'.
- Lack of safe gender sensitive abortion services.

ICMR trials done in KEM Hospital with RU486 1994 shows that 94% pregnancies terminated with: 200 mg RU486 with (1/3 of dose which was used in France) alongwith 5 mg Prostaglandin, if used within 14 days. Pregnancies were terminated in 89.6% cases if used within 28 days.

The side effects were fewer in 10% women 2 headache, 1 hypertension and 1 hepatitis.
Since 80% of the surgical abortions are done within 10 weeks, abortion pill is seen as an alternative. For women who have problems with abortion or ethical or religious bias towards the abortion some people even recommended its use once a month so that if there is a pregnancy it is terminated, if not, the only effect is slightly increased periods.

The inventor of RU486 had accused WHO, the manufacturers of the drug Roussel Uclaf of holding back the drug for fear of economic boycott by the American pro-life lobby.

Women do need private, women controlled, safe and effective means of abortion. Women health advocates are against "criminalisation" as well as "trivialisation" of abortion. Repeated abortions as a consequence of unwanted inflicted pregnancy are not always in the interest of women.

7. Ulman et al 1990 p. 42.

7.1 Gupta, J.A., New Reproductive Technologies, Women's Health and Autonomy : Freedom or Dependency ? Sage, 2000, New Delhi.

BROMOCRIPTINE

WHO Comment: Bromocriptine, a semisynthetic ergot alkaloid derivative and prolactin inhibitor was introduced into medicine in 1976. It is used in the prevention of lactation, but because of the risk of rebound effect and since only 10% of women benefit therapeutically from such intervention, the United States Food and Drug Administration has requested manufacturers to no longer indicate preparations containing bromocriptine for this purpose. The World Health Organization is not aware of similar action having been taken elsewhere.[8]

Bromocriptine

Brand	*Manufacturer*
CRIPTAL	HELIOS PHARMA
PARLODEL	NOVARTIS
PROCTINAL	GLAXO SMITHKLINE
SICRIPTIN	SERUM INSTITUTE

Buprenorphine

WHO comment: Buprenorphine, an opioid analgesic with both morphine against and antagonist activity, was introduced in 1978. It was originally considered to possess low dependence potential. However, it has lately been identified as causing a socially significant abuse problem in several countries which have consequently subjected it to control in 1989 under Schedule III of the 1971 Convention of Psychotropic substances.[9]

Buprenorphine (particularly tablet from should be banned)

Addnok	tab	Rusam Health Care
Bunogesic	inj.	Rusam Health Care
Buprinor	inj.	Astra Zeneca
Glorphin	inj.	Gland Pharma
Noophin	inj.	Dynamic
Norphin	inj.	Unichem
Pentorel	inj.	Khandelwal
Talgesic	inj.	Indus
Tidigesic	tab & inj.	Sun

CHLORMEZANONE

Scientific common name: Synonymis Chlormethazanone

Because of severe cutaneous reactions including life-threatening toxic epidermal necrolysis, Stevens-Johnson syndrome, and fixed drug eruptions, the manufacturer of chlormezanone withdrew the drug worldwide. This coincided with local action undertaken in several countries. The withdrawal concerns chlormezanone used alone or in combination.[10]

The South African Medicines Control Council has withdrawn products containing chlormezanone because of the unacceptable risk-benefit profile which is not in the interest of public health.[11]

The National Pharmaceutical Administration in the Ministry of Health has banned Chlormezanone since it has been associated with reports of life-threatening toxic epidermal necrolysis and borderline major bullous forms.[12]

Countries where banned/restricted: Worldwide, 15 November 96, UAE 1997, South Africa 1998, Zimbabwe 1998,

8. UN Consolidated List, 8th Edition, 2003, p. 42.
9. UNCPS3 United Nations Convention on Psychotropic substances (III), 1971.

Saudi Arabia June 1999.

WHO comment: Chlormezanone is a sedative with antianxiety properties and a central skeletal relaxant effect. If had already been falling into obsolescence for several years.

Brand	*Manufacturer*
DOLOBAK	B & BURK
PAMAGIN-MR	CACHET
COSMAFLAM-MR	COSMAS
SFENAC-MR	PROMPT CURE PHARMA

Indian Abortion Scenario

Estimated annual number of induced abortion varies from 0.6 (GOI, 1991-92) to 6.7 million (Chhabra and Nuna 1994). Maternal deaths due to abortion as a percentage of maternal deaths ranges from 18.1 (ICMR, 1982-83) 12.6 (GOI, 1994) 18.0% (Office of the Registrar General 1991-95).

If estimated total induced abortions are taking place between 1.9 and 6.7 million and reported MTPs are about 600,000 it is obvious that there is either under reporting of MTPs or they are taking place where adequate facilities and MTP certified doctors don't exist.

According to an ICMR study about 19 per 1000 women undergo abortion of which only 6 are legal abortions. Of the 5 million estimated abortions 4.5 million abortions are unsafe.

ABORTION PILL and PRE-ABORTION ASSESSMENT

According to the recommendations in **pre-abortion assessment and decision making for medical abortion.**

- Taking of a good gynecological, medical, social psychological history proper examination
- Investigation e.g. haemoglobin, blood group testing Rh and ABO and pregnancy test are recommended. Ultrasound is not mandatory.
- With pre-abortion counselling
- Taking of informed consent

Technology for Medical Abortion

Recommended dose for termination upto 56 days is **mifepristone** 200 mg orally on day 1 and misopostol 400 mg vaginally or orally on day 3 i.e. 48 hours later.

Clinical monitoring of vital signs and any complaints bleeding, pain, expulsion of products of conception is required for 30 minutes after mifepristone and 4 hours after misoprostol as 57% patients abort within this period.

(.....contd.)

10. SANOFI letter to Regulatory Agencies, Sanofi... 9 Oct. 1996.

11. ZAFPS Information from the Pharmaceutical Services.

12. (SGPCW) communication to WHO... 02 Aug 2000 andUN Consolidated List, 8th Edition,2003,p. 53, WHO comment p. 53-54.

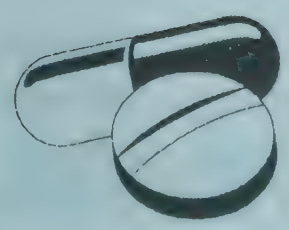
Anti D 100 mgm should be given on day 1 of mifepristone administration in Rh negative patients undergoing termination of pregnancy more than 6 weeks.

Paracetamol and codiene or nsaids can be given for pain relief.

Antibiotics are required in case of instrumentation or existing lower genital tract infection metronidazole 1 gm stat doxycycline 100 mg twice daily for 7 days.

Ref.: Proceeding and Recommendations of Consortium on National Consensus for Medical Abortion in India organised by WHO and CCR in Human Reproduction Department of Obstetric Gynecology, AIIMS in collaboration with Ministry of Health and Family Welfare, WHO and ICMR, Editor Dr Suneeta Mittal.

THE DRUG ARE SUPPOSED TO BE PRESCRIBED BY A DOCTOR UNDERTAKING PRE-ABORTION ASSESSMENT WITH COUNSELLING TAKING INFORMED CONSENT AND CLINICAL MONITORING.



7 Gazette Ambiguities

Because of the ambiguous wording of the Gazette Notification of July 23, 1983, it is unclear whether the following drugs are banned or not.

1. CAFFEINE IN TONICS

Most investigators feel that tolerance and limited degree of psychological dependence develop with caffeine and a withdrawal headache has been described repeatedly.[1]

"There is no doubt that a certain degree of tolerance and of psychic dependence develops to the xanthine beverages. The feeling of well-being and the increased performance it affords, although possibly obtained at the expense of decreased efficiency later in the day, are experiences that few individuals care to give up".[2]

COUNTRIES WHERE BANNED, WITHDRAWNN OR RESTRICTED: Not reported*

RATIONAL ALTERNATIVES: Omission of caffeine and weeding out of tonics or during a cup of coffee. (Give Gazette Notification No. 5, p. 38).

2. DRUGS CONTAINING STRYCHNINE

Strychnine is mentioned in most medical textbooks for its historical value. It was at one time prescribed liberally as a 'tonic'. Its main use has been to kill 'moles' in the field. It has been exploited deviantly by the 'Drug Culture', being 'shot' intravenously.

Despite the fact that strychnine preparations are less available than formerly poisoning by strychnine still occurs from sugar coated proprietary cathartics and tonic tablets. There are no pharmacological rationale for this dangerous practice.

There is no current justification for its presence in any medication.

3. DRUGS CONTAINING YOHIMBINE

Yohimbine has been used for its alleged aphrodisiac properties but convincing evidence of such an effect is lacking.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Cyprus, Denmark, Italy, Nepal, Philippines, South Africa, Turkey, and Venezuela.

DRUGS CONTAINING ARSENIC

EXAMPLE OF COMBINATIONS: Not available.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Italy, Philippines.

SAFER ALTERNATIVE: Drugs without arsenic

ANTI-INFLAMMATORY DRUGS WITH VITAMINS

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Bangladesh, Nepal.

RATIONAL ALTERNATIVE: Anti-inflammatory drugs alone.

1. Goodman & Gilman, 8th Edition 1991, p. 630

2. Oxford Text Book of Medicine 1987, p. 613.

TRANQUILLIZERS WITH VITAMINS

Brands not available.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Bangladesh, Nepal.

RATIONAL ALTERNATIVE: Tranquillizer alone.

Category 30 — **Fixed dose combination of antihistamine H_2 receptor antagonists with antacids except for those combinations approved by the Drug Controller of India.**

Comment: What has been approved by the Drug Controller is not known specially to the prescribers.

Category 31 — **The patent and proprietary medicines of fixed dose combinations of essential oils with alcohol, having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.**

Comment: What is in the Indian Pharmacopoeia is not known to many, nor its existence known to many. Interpretation of the ban order is left to the manufacturers, doctors' etc.

8 Know Your Medicine

Had it not been because of the continued poor status of health literacy, health awareness and health action, exploitation in the name of medicine would not have been possible. Denial of access to health care, access to essential life saving drugs would have been a major public health concern since issue of health, medicines deal with your life and life of your loved ones. Learn to protect your health.

The focussing on hazardous, banned and bannable drugs is aimed at creating public awareness about responsible use of medicine.

Very often consumers as well as the prescribing doctors are not aware of the various ingredients and their dosages in a branded pharmaceutical preparation being prescribed and consumed.

Very often prescriptions are given, and the side effects of the drugs are confused as being part of the disease and patients unaware of the side effects continue to take the drugs. Many patients even suggest the drugs prescribed to them, to others having similar problems e.g. arthritis, asthma etc. Since treatment for both the disorders is for long periods and requires prescription repeatedly, often the drugs prescribed once are continued for long, to avoid repeated and costly visits to the doctors. Steroids and steroid combinations have been prescribed for both the above conditions, but they should be used for short duration only, in certain acute conditions.

As a case study we will look closely at steroids. Steroids can be life saving drugs and have a very important role in medical treatment of certain conditions. They however, continue to be one of the most misused therapeutic category of drugs, as patients superficially tend to feel better even while infection continues within the body.

It is important for consumers to be aware, whether the brand names of drugs they are taking, contain steroids, when should they be taken? And in how much dose? How often? And for how much duration? How and when to stop the drugs?

Sometimes steroids are also being given in the name of Ayurvedic drugs, without admitting their presence. Awareness about the medicines being taken precautions to be used and side effects to be watched out for, is very essential. The various side effects are being mentioned not with a purpose of scaring but with a purpose of alerting. To avoid the avoidable drugs, to know and recognise potential problems with those drugs that are really needed is an important principle of rational drug use.

Unless considered life saving, systemic administration of corticosteroids is contra-indicated in patients with peptic ulcer, osteoporosis, psychosis or severe

psychoneuroses and they should be used only with great caution in the presence of congestive heart failure or hypertension, in patients with diabetes mellitus, epilepsy, glaucoma, infectious diseases, ocular herpes simplex, chronic renal failure, uremia and in elderly persons.

Patients with active or doubtfully quiescent tuberculosis should not be given corticosteroids except very rarely, as adjuncts to treatment with antitubercular drugs. Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged.

Corticosteroids are contraindicated in the presence of acute infections, because of interference with inflammatory and immunological response. Patients receiving corticosteroid therapy are more susceptible to infection, the symptoms of which moreover may be masked until an advanced state has been reached. Patients and relatives must be given full details of corticosteroid administration, implications of the therapy and precautions to be taken.

Concurrent administration of barbiturates, carbamazepine, phenytoin, primidone or rifampicin may enhance the metabolism and reduce the effects of corticosteroids. Administration of steroids with potassium depleting diuretics, such as thiazides or frusemide may cause excessive potassium loss.

There may be increased incidence of gastrointestinal bleeding and ulceration when corticosteroids are given with non-steroidal anti-inflammatory agents.

Corticosteroids should not be applied to ulcers of the leg and long terms topical use is best avoided especially in children and caution is required in using local application of corticosteroids in eye disorders.

Martindale 30th Edition 1993, p. 714-715.

9 Hazardous and Irrational Drugs

THE CURRENT SITUATION

It is possible to go into your local chemist's shop today looking for something to treat a simple headache, a remedy for diarrhoea, something for rheumatism, a tonic and a pregnancy test and come out with one drug that could blind and paralyse you for life, another which could deform a baby still in the womb, one more which could make your young daughter grow a moustache, and another couple of drugs which could give you a serious and often fatal blood disease. Are there no alternatives? Is it really necessary to take such risks?

Allopathic medicine recognises the potential harmful effects of drugs. Very few can be taken without any side effects, even in therapeutic doses. In deciding which drug to use, (if at all) it is important to compare the possible adverse effects the drugs may produce, and weigh them against each other, and against the risk of taking no drug at all, using alternative systems of medicines. Most important of course in the first place is an effort to prevent the disease.

Globally discarded drugs available in India

The following drugs discarded internationally are still allowed to be marketed in India.

Generic name	*Use*	*Reason for ban*	*Brand name(s)*
1. ***Analgin***	Pain killer	Bone marrow depression	Novalgin
2. ***Cisapride***	Acidity, constipation	Irregular heart beat	Ciza, Syspride
3. ***Furazolidone***	Anti-diarrhoeal	Cancer	Furoxone, Lomofen*
4. ***Nimesulide***	Painkiller, fever	Liver failure	Nise, Nimulid
5. ***Nitrofurazone***	Anti-bacterial cream	Cancer	Furacin
6. ***Phenformin***	Anti-diabetic	Acidosis (mostly fatal)	DBI, DBI-TD
7. ***Phenolphthalein***	Laxative	Cancer	Agarol*
8. ***Phenylpropanolamine***	Cold & cough	Stroke	D'Cold* Vicks Action 500*

**Denotes it is a combination product*

9. ***Oxyphenbutazonee***	NSAID	Bone marrow depression	Sioril
10. ***Piperazine***	Anti-worms	Nerve damage	Piperazine
11. ***Quiniodochlor***	Anti-diarrhoeal	Damage to sight	Enteroquinol

Analgin, Furazolidone and Nitrofurazone are banned for use in animals in the US.
Analgin is banned even in Nepal.
Ref: Dr. C.M. Gulhati, Editor, MIMS India, May 2003.

A. Dangerous Drug combinations

Only under exceptional circumstances, fixed dose combinations are allowed when (a) there is synergistic action of two drugs or (b) when there is corrective action or (c) when two or more molecules are normally needed and taken by the patient concurrently provided the dosage of each drug does not need to be individualized or (d) when combination results in better patient compliance or (e) when two or more drugs, if prescribed separately, may lead to non-ingestion of one of them adversely affecting the health of a patient. Even under such situations care has to be taken to ensure that there are no adverse interactions between the combined drugs. That the pharmacokinetic behaviour (half-life, elimination) is not grossly different, that the withdrawal of one of the agents does not lead to withdrawal symptoms and in any event sub-therapeutic doses are not used.

Why and when drugs should be banned?

1. When side effects are unacceptable for example Analgin (blood disorders), nimesulide (toxic to liver, Reye's syndrome? and safer alternatives are available (aspirin in adults, paracetamol in all age groups, ibuprofen in children over 6 months).
2. When the indications are minor and the drug is not curative such as astemizole and terfenadine in allergy (so many safer alternatives are available).
3. When superior drugs with lesser side effects are available (metformin v/s phenformin) (antidiabetic).
4. When side effects are more dangerous than the disease such as furazolidone and nitrofurazone (can cause cancer).

Countries with lax dispensing system have to be more stringent than the West. In India all drugs are sold (over the counter i.e. without prescription); so there is more need to ban harmful drugs.

When ADR reporting system is ineffective. Example: nimesulide – not one report from India while 83 from Belgium (population: 10 millions), 225 from Italy (population 58 million), 33 from Switzerland (7.5 millions) and 25 from Ireland (less than 4 millions).

Irrational Combinations: Some issues

- There is only one item on earth – medicines – where the decision to purchase and consume is not taken by the buyer but by a third party.

- Therefore theoretically if the producer of drugs and prescriber of drugs join hands and become unethical, then only the state can protect the consumers. Every day the Indian newspapers are reporting on 'cut' practices, industry-paid foreign jaunts and unethical inducements to prescribers. Hence the problem is not theoretical but practical in India.
- Quotable quote:
  The normal market forces do not operate when the "one who decides does not pay, and the one who pays, does not decide".
  A wag added "and the one who decides is often paid".
- The number of drug manufacturers in UK is less than 200 while in India it is more than 20,000.Against some 2000 brands in UK, India has over 40,000! This leads to unfair means to increase sales.
- Intense competition leads to the need to 'discover' new 'drugs' i.e. combinations because many manufacturers can not do any research because of the cost and expertise required so they 'search' for new fixed-dose combinations.
- Approval process for new drugs is defective. New molecules should be approved only if they are definitely superior to existing drugs and not merely to increase the basket size. Once an unnecessary drug is approved, its leads to unfair competition and diversion of prescriptions from essential to non-essential molecules such as paracetamol to nimesulide.
- New molecules then become the focal point for new irrational combinations such as nimesulide with paracetamol. Once such an irrational combination becomes commercially successful, in a competitive environment not only more manufacturers start marketing such dangerous combinations but find innovative methods to 'invent' even more irrational in the same direction. Example: adding tizanidine or chlorzoxazone to nimesulide + paracetamol combination.
- Irrational combinations are not only harmful to the patients (such as nimesulide + paracetamol, glibenclamide + metformin) but sometimes to communities and nations (such as ciprofloxacin + tinidazole).
- Irrational combinations lead to the so called 'off-label' or 'unapproved' use such as ciprofloxacin (anti-bacterial) and tinidazole (anti-amoebic) combinations being extensively used in diarrhoea (90% cases of diarrhoeas in India are of viral origin and need no drug treatment). Repeated use of sub-therapeutic doses of such combinations for short period's lead to development of bacterial resistance. After the typhoid germs became resistant to chloramphenicol (Chloromycetin), ciprofioxacin + tinidazole combinations, typhoid germs are becoming increasingly resistant to ciprofloxacin.Thus a whole nation is suffering due to misuse. No one knows how many people have died and continue to die to such resistance.

- The Central government's approval policy and procedures should be transparent. If necessary there should be public notification and debate.

C. Irrational fixed-dose combinations: Facts

A large number of fixed-dose combinations (FDCs) of medicines are available in India but not anywhere else. By FDC we mean a fixed amount of one drug, say A is mixed with a fixed amount of drugs say B, in one tablet, capsule or suspension. The following issues arise:

1. Drugs are discovered individually and consumed individually. Only under exceptional, specific circumstances, they are scientifically permitted to be combined. The world over there are less than 3 dozen combinations available. In India there are several hundred combinations in the market.
2. The medical meaning of 'irrational' is different from dictionary meaning. When two or more drugs are combined, their rationality has to be proved. If rationality is not proved, they are categorized as irrational. One does not have to prove irrationality.
3. As per Indian Drug laws, when two or more drugs are sought to be combined, the resultant product is deemed to be a 'new' drug and requires Drugs Controller General India, New Delhi's permission. The state drug controllers do not have the powers to approve such combinations. In practice over 90% of combinations are not approved by the DCGI. Hence they are illegal.
4. In practice this means that a resident of Delhi is made to consume a combination that is neither approved by Central Government or Delhi Government but by a State Drug Controller, say in Tamil Nadu.
5. The Dose of two or more ingredients in one tablet or capsule can not be changed to suit different patients. They all consume the same quantity – less in some cases, more in other.
6. The side effects may be additive. For example nimesulide + paracetamol combination will mean that it may adversely effect the liver twice. Since nimesulide is toxic to liver while paracetamol becomes toxic in overdose. Sometimes the adverse effect may be more than twice because medicine does not follow arithmetic.
7. The dosing interval is defective. For example nimesulide is taken 2 times day while paracetamol may need to be taken as many as 4 or even 6 times a day. How can one mix the two?
8. There can be adverse interaction in the tablet, in the stomach or in the blood when two or more drugs are mixed in one tablet/capsule/syrup etc.

D. Fallacy of Certain Arguments

1. There should be local data in India against the drug before it is banned. All 'good' data from abroad (i.e. favourable to the drug promotion) is accepted but 'bad' data (adverse drug reactions) is rejected from the same source. This is proof of double standards. Other countries do not buy this argument. Example: even though Spain had not received many adverse

reports on nimesulide, it suspended the use based on information from Finland.

2. Disease pattern in various countries is different; hence local data should be available. This argument has some merit when applied to very few disease and treatments specific to India such as malaria, leprosy, tuberculosis etc. But it is irrelevant with regard to painkillers, fever reducing agents, antidiabetics and skin creams such as analgin, nimesulide, phenformin and nitrofurazone. There is no difference between US, Finland and India.

Policy examples from sub-continent:
Pakistan's National Drug Policy requires that if a drug is withdrawn for safety reasons in the country of origin or say of the specified countries, namely, USA, UK, Japan, European Union member, then it will be banned in Pakistan unless there are some strong reasons not to do so.

Sri Lanka: considers the following drug control authorities as Reference Drug Authorities (RDAs) and clears new molecules only if cleared by any or some of them. They are USFDA, UK, MCA, TGA – Australia, Swedish Medical Products Agency (SMPA). Significantly though unfortunately, India is not on this list of RDAs. Based on this policy nimesulide was not cleared in Sri Lanka.

India: It is doubtful if post-marketing surveillance can be strengthened adequately – it requires lot of infrastructure and motivational inputs. So will have to rely on data from the West. Besides why 'bad' data from the West should not be accepted when 'good' data is?

There should be involvement of non-official agencies and individuals interested in drugs both in clearance of drugs and banning of drugs.

The system should be transparent – so people co-operate. As things stand today, some sub-committee of a committee of a Board examines and gives its decision in 2-3 lines (for example: on phenformin it was claimed "In India there is not much acidosis due to phenformin; hence the drug is allowed"). Such explanations only re-inforce the generally accepted perception that extraneous considerations prevail.

The entry of new drugs should be after thorough review and transparent. The aim should be not just increase the basket of drugs but add useful drugs.

They are more expensive in many cases. Even when they are not more expensive when purchased individually, the producers make far more money because in one strip, one carton, they have two medicines. There is no case where they are cheaper.

The cost of actual medicine in a 10-tablet strip of nimesulide is just 40 paise.

The cost of manufacture including strip, carton etc is Rs.1 to Rs.1.20.

Thus the total cost is Rs.1.40 to Rs.1.60. Sale price of some of such combinations is Rs. 40.

Therefore manufacturers love to produce FDCs.

Apart from profits, there are strong marketing reasons to combine drugs. For example one company has a large market share of anti-diabetic agent metformin under the brand name of Glyciphage, while another company sells another anti-diabetic glibenclamide in large quantities under the trade name of Daonil. Third company (Sun Pharmaceuticals) wishes to enter the market. Instead of competing with the two already well-established brands of individual drugs, it creates a 'third' drug by combining the two under the trade name of Glucored. The patient is the sufferer because of quantity of two drugs is inflexible and he may be consuming one drug too much and the other too little.

Scientific calculations show that the chances of the patient consuming the right quantity of each drug is less than 11%. Hence 89% patient are consuming wrong quantities. How many patients are suffering from such FDCs no one knows.

Some of the Fixed Dose Combinations (FDC's) of Questionable Rationality

Atorvastatin + Amlodipine
Mosapride + Pantoprazole
Tamsulosin + Finasteride
Atorvastatin + Niacin ER
Vitamin + Acetylcystine
Domperidone + Omeprazole
Domperidone + Pantoprazole
Pioglitazone + Metformin (Extended Release)
Roxithromycin + Serratiopeptidase
Domperidone + Ranitidine
Rabeprazole + Domperidon
Clopidogrl + Aspirin
Atorvastatin + Aspirin
Glibenclamide+Metformin+Rosiglitazone
Isosorbide Mononitrate + Aspirin
Ramipril + Amlodipine
Tranexamic acid + mefenamic acid
Alprazolam + Paracetamol
Losartan + Atenolol
Sertraline + Alprazolam
Mebeverine + Alprazolam
Gatifloxacin + Ornidazole
Ofloxacin + Tinidazole + Lactic acid bacilli
Famotidine + Domperidon

Fluroquinole use in children is not advisable. Ciprofloxacin has been controlled by the FDA, and earlier syrup & DT 100 mg products of Cipro have been withdrawn. However, now following are available in the market:

1.Ofloxacin suspension
Ofloxacin + Metronidazole suspension
Ofloxacin + Ornidazole suspension

Source: Dr Raj Vaidya, M.Pharm, Community Pharmacist, Hindu Pharmacy, Goa.

Reproduced: Dr C.M. Gulhati, Editor, MIMS India, October 2000.

Why risk our children to Nimesulide?

Dr. Wishvas Rane

Nimesulide, a US discovered drug, is prohibited for use in America. It was synthesized by American 3M Pharmaceuticals. It is known that USFDA (United State Food and Drug Administration) is quite strict and thorough in processing new drug applications. An argument is being made that Nimesulide was not introduced into US market because it is 'out of patent'. The drug could not have been out of patent at its time of discovery. Why should an American discoverer after spending hundreds of millions of dollars on research not launch it in the biggest market of medicines on earth unless it was known that the drug did not meet efficiency and safety requirements?

Nimesulide was sold to Helsinn, a small privately owned pharma company in Switzerland. However, Helsinn failed to introduce it in Switzerland. It was then licensed to another company Boehringer for introduction in Italian market in 1985. After human use and experience in Italy. Nimesulide was introduced in Switzerland but only in tablet form, and that too only for adults. Till today the drug is not permitted for use in children in Switzerland.

In India, every 'new medicine' is approved just because it is new. There was no justification for nimesulide's approval. For taking marketing approval from DCGI (Drug Controller General of India) Under Rule 122 (E) and Schedule Y it is obligatory to get animal and human clinical tests done in India in respect of new drugs. In exceptional cases and in public interest, the DCGI may waive the requirements of clinical trials, if adequate data in the form of published studies is available from other countries.

Published studies mean research articles in reputed independent journals like *Lancet, New England Journal of Medicine, Journal of American Medical Association and British Medical* Journal. Incase of nimesulide the only published studies given to DCGI were publications brought out by Adis International Ltd. a private company in New Zealand (Where nimesulide is not approved) Adis does not make any secret of its close ties with pharma industry and acknowledges that its aim is to serve pharma industry. Obviously, such published studies lack credibility and are not free from bias.

The mandatory regulatory requirements were not met before issuing marketing approval for nimesulide. The drug was hastily approved in violation of established rules. The first application of marketing permission (Under Rule 122-B) along with permission to import the drug (Under rule 122-A) was made on 1 December 1994, and the approval letter was issued on 13 January 1995 As such, nimesulide would need to be considered as a new drug for 4 years upto 13-01-1999 and all other formulations (shown in Table) had to obtain DCI approval for introduction to market. No such approval was obtained in marketing all the

formulations and FDCs. This is a clear violation of Drugs and Cosmetics Act and Rules.

The DCGI gave permission for only 100mg plain tablet. As per the definition of a new drug, all formulations except 100mg plain tablet need DCGIs approval. We can find that there are 8 different tablet forms, and 9 different FDCs with other drugs. These are all illegal formulations. The 9 different FDCs have 25 different formulations and FDCs have 25 different formulations (strengths) and its over 255 brands and packing.

The drug was initially claimed to offer equivalent anti inflammatory and analgesic effects without causing gastrointestinal injury. At the faculty of Medicine, University of Calgary, Canada, it was established that inhibition of both COX 1 and COX 2 is required for gastric injury. Research found that apart from COX 2 nimesulide was also inhibiting COX 1 to some extent. Therefore, the earlier claims of exclusive COX 2 selectivity was modified to preferential inhibition of COX 2 (Gastro-enterology 2000 Sept. 119(3) 706 –14).

In usual dosage (5mg/kg per day) nimesulide mean serum concentration reaches 14.6 mH. However, only 1.49 mH concentration is required to effectively inhibit gastric COX-1 activity leading to the possibility of ulcer formation (AM J Med Ass 1998: 104:413-21). That means that much before anti-inflammatory and analgesic effect is produced by nimesulide, gastric effect is dominant and gastric mucous is adversely affected. In a well-validated study Wallace JL et al found that nimesulide's anti-inflammatory activity correlated with COX 1 and COX 2 inhibition. At doses required to produce effective anti-inflammatory and analgesic activity, nimesulide's gastric damage score was found to be no better than indomethacin (Gastroenterology 1998: 115:1-1-9)

Role of COX 2 in the renal and cardiovascular systems are becoming better recognized. Inhibition of COX 2 can lead to peripheral oedema, hypertension and thrombosis. Recent evidence suggests increased rates of myocardial infarction in patients of nimesulide therapy. (Dig Liver Dis.; 2001 Dec.: 33 Suppl: 2: 52108). It has also been established that anti-inflammatory efficacy of nimesulide is inferior to that achieved with NSAIDs that inhibit both COX 1 and COX 2 (Am J Med Ass 1999 Dec. 13:17(6).

If an unessential drug is not sold in its country of discovery or is banned or not approved for safety reasons in many advanced countries with good ADRs (Adverse Drug Reaction) monitoring system, it is the moral ethical and statutory duty of DCGI to first suspend the use of the suspected drug and then order review of the safety profile of the drug. Life and health of the people is more important than the convenience of the drug companies.

Countries with lax dispensing systems have to be more stringent in controls than

the West. In India where most of the drugs are available on OTC, the need to ban harmful drugs is more. ADR reporting and monitoring system in India is very poor. This is obvious from the fact that not a single adverse reaction to nimesulide has been reported in India, whereas 83 from Belgium 225 from Italy, 33 from Switzerland and 25 from Ireland have reported adverse reactions to nimesulide.

The DCGI has informed the Lok Sabha (starred question No. CP –116.4386 dated 21-08-2000) that nimesulide + paracetamol combination does not have his approval. The DCGI in his affidavit filed in the Delhi High Court has acknowledged that state drug controllers are issuing licenses indiscriminately. The DCGI claims that nimesulide has been designated as a 'prescription drug and hence cannot be legally sold without prescription. Eight years have passed since nimesulide's approval for marketing and no schedule has been given to nimesulide. There is no provision in the Drugs and Cosmetics Rules to merely state to be sold on prescription of registered medical practitioner 'without giving a schedule to the drug' Paracetamol is an OTC drug and nimesulide has no schedule and thus a combination of nimesulide and paracetamol though illegal and hazardous, can be sold without a prescription. No wonder the total sale of nimesulide and its FDCs were Rs. 211.24 crores in the year 2001.

The price of nimesulide (100mg 10 tablets) varies from Rs. 7.90 (Nisulide of Emcure) to Rs. 29.00 of Panacea Biotec. But the maximum seller is not the cheapest brand but a costlier 'Nise of Dr Reddy's costing Rs. 25.74. In the year 2001 sale of Nise tablets was Rs. 49.47 crores which is 33 per cent of the total tablet sale. If nimesulide was under price control, taking all expenses into account the NPPA (National Pharmaceutical Pricing Authority) would have allowed a retail price of Rs. 5.00 for 100mg 10 tablets. In fact Cipla sells a strip of 10 tablets nimesulide (Nicip) to chemists at Rs. 2.20.

Therefore, the real issue before the drug companies engaged in selling nimesulide (either alone or in combination) is the profit and not the need of the patients or the safety of the drug.

The hepatotoxic effects of nimesulide have been known for some years though not adequately published. For this reason the drug is not approved in most countries having large markets for medicines viz. United States, Britain, Australia, New Zealand, Canada etc Six applications to market nimesulide in Sri Lanka were rejected by their government. The drug is not approved in Bangladesh and Pakistan. Two children taking nimesulide died of Reye's syndrome in Portugal leading to a ban on paediatric suspension in that country in 1999.4

Irrespective of whether nimesulide is or is not hepatoxic, does or does not cause Reye's syndrome, why should we take the risk when nimesulide is not very essential or monopoly medicine for a serious life-threatening disease like tuberculoses, malignancy or AIDS? If a known safer antipyretic like paracetamol is cheaply

available, why risk our children to nimesulide?

Source: Dr Wishvas Rane in Health Action, 2003.

FIXED DOSE COMBINATIONS OF NIMELSULIDE BEING MARKETED WITHOUT DCGI APPROVAL

i) NIMESULIDE + PARACETAMOL.

Brand	*Manufacturer*
ACILID PLUS	ALLURE REMEDIES
ARTIFEN	AGLOWMED
BASELIDE-PLUS	ULTRAMARK
BESTOGESIC PLUS	BESTOCHEM
DEEMULID-P	DEETECH PHARMA
DIPLONIM-P	PHARMATECH
DOLAMIDE	RANBAXY
DOLOFLAM PLUS	VILCO
DOLONIM-P	BIPL
DOLPRIN	RELISH
EMSULIDE-P	EMCURE
EMULIDE P	ZINET
GESNIM –P	AARPIK PHARMA
MANLIDE-P	SHALMAN
MINISULE PLUS	MANISH PHARMA
NELSID PLUS	IND-SWIFT
NEMERIV-P	EAST AFRTICAN ®
NEPAR	RUSAN
	HEALTH0CARE
NIAP	AMERICAN
	REMEDIES
NICALID-P	REPLICA REMEDIES
NIDE-P	NECTAR PHARMA
NIMAT PLUS	ATOZ PHARMA
NIMEB-P	TAURUS LABS
NIMESON-P	UNISON PHARMA
NIMETEC PLUS	TALENT LABS
NIMEX PLUS	LANARK LAB
NIMICA PLUS	IPCA
NIMIL PLUS	SHAIMIL
NIMIZ PLUS	ZOTA
NIMOOL – P	ONTARIO
NIMSAID-P	MEDLEY
NIMUZEN PLUS	ZENITH
NIMVID – P	VIVID LABS
NIPAR	AXON HC
NIQ – P	QUE PHARMA
NOBEL PLUS	MANKIND
	PHARMA
NOCK 2	WANDER
NOFLAM P	EUPHORIC
N S PLUS	PHOEBUS
PAIN LOCK	VIP PHARMA
PARANIM	ALLIANZ HC
PARASHOOT	NATIONAL
	CHEMICAL &
	PHARMA
PARAZOLANDIN	SARABHAI
	PIRAMAL
REMUDOL	RECON
SALAPAIN	KEE PHARMA
SOLID P	BRAWN
SULID P	SHINTO ORGANICS
SUMO	ALKEM
ULTRAMIN	BIPL (RADICO
	REMEDIES)
ZIMULIDE – P	ZINET

ii) NIMESULIDE + PARACETAMOL + TIZANIDINE

Brand	*Manufacturer*
BESTOGESIC MR	BESTOCHEM
TRIZONE FORTE	ZEE LAB

iii) NIMESULIDE + PARACETAMOL + CHLORZOXAZONE

Brand	*Manufacturer*
NIMPAC	SYSMED
NIMZOX – P	RAPROSS PHARMA
SIES-NMR	SIESTA PHARMA

iv) NIMESULDIE + DECLOFENAC

Brand	*Manufacturer*
EMSULIDE-FEN	EMCURE

Brand	*Manufacturer*
NIDEGESIC	VIP PHARMA

v) NIMESULIDE + DICYCLOMINE

Brand	*Manufacturer*
AVOSPAS	SHREEYAM
	HEALTH CARE
COMSPA	COMED
CYCLOLIDE	SHALMAN

LIDSPAS	AXAR PHARMA
MENARK	SYSMED
NIDASPAS	VIP PHARMA
NIMSPA	OBSURGE
NIMUSPAS	STEDMAN PHARMA
NISE SPAS DS	DR REDDY'S
SPASFREE	GRANDIX

vi) NIMESULIDE + CHLORZOXAZONE

Brand	*Manufacturer*
NAM PLUS	LINCOLN
NIM-MR	VARUN
	CONTINENTAL
NIMOZOX	WENS PHARMA
NIMUZOX	STEDMAN PHARMA
NIMZOX	RAPROSS PHARMA
NIZOX	GRANDIX
NUCIL	ADLEY LAB

vii) NIMESULIDE + TIZANIDINE

Brand	*Manufacturer*
AVOLIDE T	SHREEYAM HEALTH
	CARE
DEEMULID –T	DETECH PHARMA
DOLONIM MR	BIPL
ITZGON	KEE PHARMA
MOZTIN	EAST AFRICA ®
NESTA	PROCHEM
NIMCOM- MR	COMED CHEMICAL
NIMENT MR	ASCENT LAB
NIMETIZ	AJANTA
NIMSTAL PLUS	INDCHEMIE
NIMUBEN TZ	BANTOM LAB
NIMULID MR	PENACEA
NIMZONE – MR	WOODROCK
NIPACE- MR	FEMCARE
NIXIA MR	WANDER
NOBEL MR	MANKIND
Brand	*Manufacturer*
OXIN – MR	SYNOKEM
SIENA	SIESTA
TEKNOFLEX	DWD
TIZA N	MEDIWIN
TIZANIM	ALKEM (BERGEN)
TIZED M	TALENT INDIA
TIZILEX	PROFIC ORGANIC
TIZPA N	BLUE CROSS
TIZU	INDOCO
TIZULID	BIPL
ZELID TZ	ZEE LAB
ZENIM MR	UNIVERSAL
	MEDICARE
ZULU	UNICHEM

viii) NIMESULIDE + CAMYLOFIN

Brand	*Manufacturer*
ANAFORTAN N	KHANDELWAL

ix) NIMESULIDE + SERRATIOPEPTIDASE

Brand	*Manufacturer*
EMANZEN N	EMCURE
KINETO N	SYSTOPIC
LYTIC N	WENS PHARMA
MAXIFLAM	KARNATAKA
	ANTIBIOTICS
NELSID S	IND SWIFT
NIMDASE	OBSURGE
NIMOOL SP	ONTARIO
NIMSAID S	MEDLEY
NIMSER	ARVIND REMEDIES
NIMUDAZ	SRESASN PHARMA
NIMULASE	TTK
NIMULID SP	PANACEA
NIMVON S	AJANTA
OPTASE NH	OSPER PHARMA
OXIN PLUS	SYNOKEM
SERANAVI	SPECIALTY
	MEDITECH
SERATODASE N	MARC LAB
SERETAUR N 10	TAURUS LAB
SERNIM	SYSMED
SERULID	BIPL (REDICO
	REMEDIES)
STALWAR N	PROFIC
ORTHOZEN	LITAKA PHARMA
MAXIFLAM SP	KAPL

x) NIMESULIDE + METHOCARBAMOL

Brand	*Manufacturer*
ROBILID	KHANDELWAL

xi) NIMESULIDE + P – PIPERIDINOETHOXY – O-CARBOMETHXYBENZ OPHENONE + DIPHENYL PIPERIDENOETHYL

ACETAMIDE + BROMOMETHYLATE.

Brand	*Manufacturer*
NOVIGAN N	DR REDDY'S

xii) NIMESULIDE + DROAVERINE

Brand	*Manufacturer*
NOBEL SPAS	MANKIND

xiii) NIMESULIDE +CETRIZINE + PSEUDOEPHEDRINE

Brand	*Manufacturer*
NAM COLD	LINCOLN

DANGEROUS DRUGS WHICH SHOULD BE SEVERELY RESTRICTED

Many drugs are useful only in certain indications – they are unnecessarily harmful in others.

Anabolic steroids (synthetic male hormones) form one category of drugs which are often used to treat conditions for which they are both useless and dangerous. These drugs are only useful as supportive therapy in treating certain rare conditions such as aplastic anaemia (bone marrow shut down), where the patient is very seriously ill. Instead, anabolic steroids are widely sold as tonics and growth stimulants for malnourished children – they are even listed under the 'Nutrition' section of the commercial drug prescribing guides. As tonics, they are not only useless but also dangerous. Anabolic steroids can actually stunt growth in children by prematurely closing the epiphyses (the growing ends of bones). Moreover, the sexual development of children who take these 'special' tonics can be seriously disturbed. Young girls can develop masculine characteristics such as deepening of the voice and facial hair, which are all the more distressing since these effects are irreversible. The best treatment for poor growth or underweight is course good nutritious food, not expensive drugs, yet well-meaning parents and ignorant doctors continue to give anabolic steroids too help the child grow, oblivious of both the dangers and the futility. Furthermore, a malnourished child very often comes from a family which can least afford to waste its meagre income on expensive medicines.

Dangerous drugs like anabolic steroids which are advisable only in specific life-threatening situations should be very severely restricted to only those situations. Some of the other drugs which were very commonly misused were chloramphenicol and streptomycin.

DANGEROUS AND IRRATIONAL DRUGS WHICH SHOULD BE BANNED OR SEVERELY RESTRICTED

There are some drugs which are never useful - their benefits never outweigh their harmful effects under any circumstances. This is either because safer alternatives are available, or because the drug is simply useless, or both.

Hydroxyquinoline Clioquinol was another highly selling drug which was used to treat diarrhoea and commonly known as the 'Khaki tablet', the colour of the leading brand, then Enterovioform.

Eleven thousand people in Japan alone were afflicted with the very serious

neurologicalside-effects of this drug. Intoxication with Clioquinol has been reported from the USA, Canada, France, Switzerland, Federal Republic of Germany, Austria, Sweden, Denmark, Netherlands, Finland, Belgium, Poland, Spain, Italy, Iran, India, Indonesia, Brazil, Israel, Lebanon, Argentina, Australia.

Clioquinol damages the nervous system, and can result in paralysis, blindness and loss of bladder control, often accompanies by great pain in the limbs. The manufacturer of the drug consistently denied that the drug was absorbed and therefore could not cause neurological complications. Late Dr. Olle Hansson, paediatric neurologist from Sweden challenged this. He gave evidence on behalf of the victims. It was due to his contribution and socially conscious lawyer Izumi and their persistent efforts that resulted in the victims being paid compensation in an out of court settlement. It was taken up in the courts and after a long hearing with evidence from internationally renowned experts, the verdict was given (1971) that the suffering of these victims was due to clioquinol. The drug companies (Ciba Geigy, Tanabe and Takade) were found responsible for sales of these drugs while failing to inform doctors and the public about their hazards. Very soon afterwards, other countries stopped using the drug, which has now become obsolete in many part of the world. The Government of India did likewise, and banned clioquinol (D.O.X. 19013/8/81-D August 13, 1982).

However it was not long before the ban was superseded by another Gazette Notification (DO No. X 110114/1/83-DMSOPFA July 23, 1983) which excluded from the ban all preparations intended to treat diarrhoea, and those intended for external use (clioquinol is safe for external use). So the purpose of the original ban (to prevent the suffering caused by clioquinol) was entirely defeated and diarrhoea sufferers continue to risk their health by taking this unnecessary drug. Again the people who suffer the most from diarrhoea (those who do not have safe drinking water, sanitation and enough food) are those who can least afford the harmful and debilitating effects of clioquinol. Ironically, they remain unaware of the cheapest and most effective treatment, oral rehydration solution, made at home from sugar, salt and water and in case of amoebiasis - anti-amoebic drugs which are effective not just against amoebae in the gut lumen but also the crypto and infection in the gut wall.

Analgin is another dangerous drug recommended for banning (as a fixed dose combination) by the Drug Consultative Committee in 1980. However, analgin is one of the most popular over-the-counter drugs, and is far better known to the general public than its safer and cheaper alternative, aspirin. It is the sodium sulphonate of amidopyrine, banned by the Government in 1983, and can cause the same blood disease, agranulocytosis (see glossary), which is often fatal. Since these hazards have been discovered, amidopyrine and analgin have almost disappeared from other countries and become obsolete. Even standard

pharmacology textbooks refer the reader to earlier editions to find information on these drugs.
Analgin as an analgesic, antipyretic and anti-inflammatory agent carries far more risk of serious side effects than paracetamol or aspirin, given properly, which are just as effective.

The sub-committee of Drug Consultative Committee also recommended in 1980 that fixed dose combinations of analgin be weeded out. The Drugs Technical Advisory Board in 1982 deleted this from their recommendation. Analgin combinations were recommended for being weeded out by the subcommittee of the Drug Consultative Committee under the Chairmanship of Dr. Patel, Commissioner, FDA, Gujarat, which met in 1988. Analgin combinations were banned only in 1995.

Analgin and analgin combinations with antispasmodics have been ironically excluded from the ban.

Another drug which has achieved international notoriety, but which is still commonly available in India, is **oxyphenbutazone.** The Government has to yet attempted to ban it. The firm which discovered the drug in the 1950s, Ciba-Geigy, has withdrawn from the world market this product, sold under the brand name Tanderil. It has caused over a thousand deaths worldwide, and has been replaced by far safer alternatives. Its close relation, phenylbutazone which has very similar side-effects, has been recommended by the Drug Control Authorities of India only for ankylosing spondylitis and acute gouty arthritis and even then, only as a drug of second choice. Yet, sales of oxyphenbutazone and phenylbutazone under several brand names continue unrestricted.

RATIONAL COMBINATIONS

FIXED DOSE COMBINATIONS INCLUDED IN THE WHO LIST[1]

Benzoic acid	+ Salicylic acid
Carbidopa	+ Levodopa
Ethinylestradiol	+ Levonorgestrel
Ferrous Salt	+ Folic Acid
Isoniazid	+ Rifampicin
Isoniazid	+ Thiacetazone
Neomycin	+ Bacitracin
Sulfadoxine	+ Pyrimethamine
Sulfamethoxazole	+ Trimethoprim

With very few exceptions (e.g. the above) fixed dose combinations are unnecessary: single ingredient drugs are just as effective and cheaper. It is impossible for doctors to remember the ingredients and proportions of so many formulations and this leads to confusion in prescribing, and increases the chances of drug interaction. On top of this, reformulations are made without any systematic way of informing the doctors as well as chemists of the change.

Many of these combinations are irrational in themselves. Anti-diarrhoeal drugs often contain ingredients which are hazardous not only present in sub-therapeutic amounts, but which are useless in the treatment of diarrhoea anyway.

Very few **tonics** include the correct proportion of vitamins and minerals, although they often contain alcohol. Food

is the best way to overcome vitamin or mineral deficiency. There are tonics in the market even for newborn babies, when all that a baby needs for the first four months of life is contained in exactly the right proportions in mother's milk, even if the mother is malnourished herself.

Decreasing knowledge about nutritive value of foods and increasing use of nutraceuticals is evident.

Decreasing concern about nutritive value of food and food availability in a country where over 80% pregnant women are anaemic, 1/3 new borns are Low Birth Weight (LBW) babies and 52% under fives are malnourished. Greater focus continues on 'microneutrients' availability of which from pharmaceuticals rather than natural foods is encouraged.

Food substitutes like Glucose D, Glucon-D are widely sold at high prices even though glucose and vitamin D are far more cheaply obtained from food and sunlight.

Painkillers many of which can have serious side effects are often combined with an amount of caffeine too small to have any therapeutic effect on the human body, and is not useful in relieving pain, either. The Gazette Notification ban included the useless combination of analgesis with vitamins. People are paying higher price for irrational and unnecessary additions to the drug they need, and consuming drugs that can have serious side effect of bone marrow depression fall in white count. Many painkillers - Nonsteroidal anti-inflammatory drugs stomach by some one suffering from peptic acid disease - bleeding can occur.

The arrangement obviously holds no medical benefit whatsoever, and only leads to the exploitation of those who have very little money to pay for their medicines, and next to no information on which medicine to choose. Many poor villagers buy a few tablets at a time, and the difference of 50 paise to 5 paise per tablet is a very real difference to them. There are many other instances of irrational combinations of more expensive and sophisticated drugs.

Wastage of scarce resources is not only taking place on an individual level but at a national level. With continual shortages of essential drugs in our country, it is shameful to be using our well-developed pharmaceutical industry to produce such huge quantities of irrational and useless combinations. Banning such preparations along with hazardous drugs, and encouraging the production of those medicines which we do need, would be a big step towards rational and people-oriented health care.

BANNED DRUGS

WHEN IS A BANNED DRUG NOT BANNED?

Firstly, when the Government decides (in effect) to lift the ban, as in the case of clioquinol. (Hydroxyquinoline) Haemoglobin products which were banned, unbanned and then rebanned.

Secondly, when the drug companies, who

1. WHO Technical Rep. Ser. 825, 1992.

(NSAIDS) taken during Dengue Haemorrhagic fever resulted in severe bleeding, plain Aspirin, safe in other circumstances but when taken on empty stand to lose from the ban, obtain a stay order on its products and Government itself fails to vacate the stay order. High dose EP drugs were banned in June 1982 but due to the stay order ban was lifted and ultimately banned in 1988.

Thirdly, when the ban is diluted, so as to leave out some hazardous drugs.

The banning of steroid combinations initially by DCC* excluded steroid combinations intended for asthma by DTAB. The result was that steroid combinations previously indicated for other illnesses were suddenly recommended for asthma, while usage for earlier indications, continued also.

Fixed dose combination of chloramphenicol was recommended for banning by DCC in 1980. It was diluted by the DTAB to Chloramphenicol combination, excluding Choloramphenicol and Streptomycin combination.

Fourthly, when a ban order is ambiguously worded, leaving room for loopholes. The Gazette Notification of July 1983, failed to specify whether a drug would be banned only if all ingredients or if any of the combination of ingredients were present. E.g. Yohimbine strychnine in Testerone in tonic as in category 5 Gazette Notification.

Failure to specify meaning of steroid combinations as to whether it would include anabolic steroids and listing of the specific drugs.

Wording the Gazette Notification in such a way that injectable preparation is left out when the preamble clearly states that the formulations are harmful and have no therapeutic value. But only oral dosage forms are mentioned in the section having legal status. Thus giving an impression that all formulations are banned (injectables and tablets) yet banning only the latter. E.g. Fixed dose combination of Estrogen Progestine, high dose oral formulation.*

Fifthly, when the ban order is not enforced. When the legislation is inadequate. E.g. The 22 categories of banned drugs could not be banned till the Drugs and Cosmetics Act was amended following which alone was the Gazette Notification issued in July 1983.

When the ban order is issued in a Gazette Notification and no effort is made to use the government media e.g. AIR, Doordarshan as well as major national dailies to publicise the drugs and the brands involved. E.g. Astimazole, Terfenadine and Phenformin have apparently been banned in 2003 but most doctors consumers are nor aware, nor have they been incorporated in the website.

When name of brands and the manufacturers of the banned drugs is not made public to prevent doctors from prescribing and consumers from consuming them.

When authorities concerned fail to ensure withdrawal of stocks from the manufacturers and the market.

**DCC - Drug Consultative Committee*

When authorities concerned fail to seriously monitor the continued sales of banned drugs.

Sixthly, when authorities concerned consistently fail to punish those who violate the ban orders.

An urgent stock taking and screening and listing of all the drugs in the market is required.

Identification of hazardous and also irrational and non-essential drugs in required.

Withdrawal of these drugs should take place immediately.

Deterrent punishments of those who continue to sell banned drugs and challenge the decision of the Drug Controller and the Drug Consultative Committee.

The list of irrational drugs to be banned is too long since a majority of the drugs available in the Indian market are irrational. This is indicated by all the studies that have been carried so far of different types of drugs available in the market – tonics, antidiarrhoeal cough and cold preparations, iron-haemoglobin tonics, over the counter drugs etc. It is not expected of the Supreme Court to undertake the huge technical task of going through the irrationalities of each category of drugs. The Central Government had already appointed in 1987, an 'Expert Committee' on weeding out irrational/ harmful/sub-therapeutic drugs. **It may be noted that the government can ban not only hazardous drugs but under Section 26 A of the Drugs & Cosmetics Act 1940, the government can ban those drugs which "do not have the therapeutic value claimed for them or contain ingredients and in such quantity for which there is no therapeutic justification".** It is strongly felt that the Expert Committee report should be made public.

1. Such a Committee should function far more effectively and efficiently, since hundreds of drugs belonging to dozens of categories need to be evaluated to weed out the irrational/ harmful/subtherapeutic drugs and drug combinations.
2. The Committee should accept the following principle for weeding out drugs – all drugs or drug – combinations, which have not been recommended by standard text books of pharmacology or medical sciences.

IRRATIONAL DRUGS: ATTEMPTS AT BANNING DRUGS

The irrational drugs on the market are too numerous to list here. Most of the 60,000 formulations (20,000 formulations as per the Mashelkar Committee Report on strengthening drug regulation, November 2003) available are combinations of two or more drugs, with very few exceptions (e.g. the oral contraceptive pill). *See Box in page 108.*

*Note *This was later changed to include injectable preparations also after protests.*

During the hearing on 8th May 1994, the Supreme Court asked the petitioners (Drug Action Forum, Karnataka All India Drug Action Network, and Delhi Science Forum) to submit the list of drugs that the petitioners wanted to see banned. (PIL No. 698/1993 in S.C.) or by WHO, should be banned. This principle is quite scientific and practical. The rationale behind this principle is:

Firstly, poor countries like India cannot afford the luxury of unscientific formulations not recommended by standard textbooks of pharmacology or by WHO. A study has estimated that 63% of the money spent by patients on drugs is wasted due to irrational drug use.

Secondly, the unnecessary drug or drug in a wrong dose in these unscientific drug formulations pose an unnecessary health hazard in the form of 'iatrogenic disease'.

Thirdly, it is almost impossible for the drug-authorities to do the quality control testing of these hundreds of formulations, containing thousands of different ingredients in different proportions. So is the case with the monitoring of their prices.

The Supreme Court, in its judgement in the case of Vincent Penikulangara Vs Union of India (1987, 2 SCC, p. 165), had directed the government that there should be adequate representation on behalf of he consuming public on the Drugs Technical Advisory Board. Prompt action should be taken to suitably amend laws to authorise such representation both on the Technical Board as also the Consultative Committee. The government has not followed up this recommendation of the Supreme Court. The Supreme Court should order the government to carry out this directive immediately and include one of the experts from the petitioners/co-petitioners on the Expert Committee.

Just as it is considered that there is no need to carry out clinical trials to assess the rationality, effectivity in 'Indian condition' of any particular new drug or drug formulation being introduced in the Indian market. Like wise there is no need to assess the incidence of adverse effects of a particular drug (like say analgin or clioquinol) in 'Indian Conditions' before banning the same. Sufficient international evidence is available to assess the efficacy and/or safety of these drugs. Genetic differences should not be a cause to withhold banning of a drug if it is already banned by the advanced countries or by the parent research companies. Secondly, if clinical trials were not conducted to decide the efficacy of these drugs in 'Indian conditions' while introducing these drugs, why should clinical evidence of hazardousness be sought before banning the drugs?

Particular care should be taken by these committees and by the Drug Controller of India, that the recommendations and the Gazette notifications should be

precise and not have ambiguities of wording to leave loopholes for the companies to exploit. Such loopholes have also delayed the implementation of the ban-orders in the past.

No extended prior notice should be given to drug companies before the ban notification. Such prior notice was given by the Drug Controller of India per his circular dt. 8th February 1994, about the impending ban on irrational antidiarrhoeals. In this circular, the Drug Controller has clearly mentioned that the letter was sent to enable the drug companies to plan their marketing strategies, so as to withdraw the stocks of subject drugs from the market before the Gazette notification is notified. This is an objectionable practice. Once the Drug Controller is satisfied that particular categories of drugs need to be banned, no prior notice should be given to the manufacturers about the impending ban where hazardous drugs are considered, where non essential are concerned, opportunity to withdraw, rationalize formulation. It is sufficient to give 1-2 months for the manufacturers and stockiest, chemists and pharmacists to withdraw their stocks after the ban order. In case of irrational antidiarrhoeals, more than seven months passed after this notice (8 Feb. 1994) and the gazette notification had not been issued till mid September 1994. Besides prior notice can be misused by manufacturers to create legal hurdles in the ban order.

Banning of Drugs

Dr. P.K. Sarkar

International Scenario

From time immemorial human kind experimented with many substances for their healing power. Those agents (herbs and other natural products) had been found to be effective were included in the therapeutic armamentarium of the geographical location concerned. However, search for agents endowed with better healing power continued over the ages. During the infancy of Western (allopathic) medicine, almost all the drugs were derived from plants (e.g. opium, ipecac, digitalis, cinchona, ergot to name a few), minerals (Epsom salt, iron etc.) and animals (e.g. thyroid extract). With the development of chemical (dye) industry in Europe and discovery of synthetic chemicals having medicinal properties and evolution of pharmaceutical houses the scenario changed very rapidly. Drug companies not only started marketing a large number of synthetic patent and proprietary medicines but in the process also usurped the compounding and dispensing functions of the pharmacists (previously called compounders).

Hundreds of substances (drugs) were brought to the market without testing their effectiveness and safety. Existing laws regarding manufacture and marketing of pharmaceuticals had very little power to curb this practice until a major tragedy broke out in the USA in 1938. A large number of children died after

consumption of a syrup of a 'sulfa' drug. Analysis revealed that that liquid in which the drug was dissolved contained diethylene glycol, a dangerous chemical which damages the kidneys leading to death of the subject. This necessitated amendment of the Drugs Act in the USA by way of inclusion of the safety clause. Thereafter, it became mandatory for the manufacturers to ensure that whatever products they brought to the market, were safe.

If a product (drug) is marketed which is safe but does not do any good then the whole purpose of its use as a drug is defeated. Subsequent to this realization, and in order to prevent the circulation of useless substances masquerading as drugs, the Drugs Act in the USA was again amended to include the efficacy clause which mandated that it is not enough for a product (drug) to be safe, it has to be also effective for the condition for which it is advocated.

The US Congress (Parliament) appointed a committee to screen all the existing drug formulations marketed in the USA on the basis of those two amendments i.e. any substance marketed as drugs in that country has to be safe and effective. Many drug companies failed to produce evidence of effectiveness in support of a large number of drug formulations available in the country hence marketing license for those products were cancelled (banned) and the drug companies concerned immediately removed the banned products from the market. Many countries also undertook similar exercise to weed out (ban) useless and/or harmful drugs from their market. In 1982, Bangladesh had screened all the available allopathic drug formulations on the basis of effectiveness, safety and essentiality and removed (banned the manufacture and sale of) about 1735 products from the market. These included vitamin tonics, cough syrups enzyme preparations, clioquinol, combination of analgesics, to name a few.

A United Nations Agency also published a monograph showing the list of drugs banned in different countries the world over.

Indian Scenario

Medical science recognizes and recommends only about 600 drugs but the Indian Market sells more than 60,000 items of drugs. The absurdity of such a massive inflation of numbers has been possible due to a number of devices e.g., random unscientific and irrational combination of drugs posing as new drugs which are unnecessary and often harmful; persistence of obsolete drugs; licensing of unscientific herbs and indigenous materials as drugs, and multiple brand-name formulations of a single drug.

It must be emphasized that unscientific drugs (i.e. drugs not included in medical textbooks) are neither taught to the medical students nor are they necessary for rational medical practice. These unscientific combinations are the brain children of the drug-traders and unfortunately approved by the licensing authority. The medical practitioners are then brainwashed and

allured to prescribe those drugs. And this is the chief source of illegitimate profit of the drug industry. If these unscientific combination drugs are removed and only scientific drugs, as recommended by medical science, are allowed in the market, following beneficial effects will be forthcoming.

i. Protection of Health of the People: Today innocent people are continuously being subjected to loss, both physical and financial, caused by unscientific harmful drugs. This menace will disappear.
ii. Curbing the illegitimate profit of drug traders: Maneuvering of the drug companies for illegitimate profit is chiefly confined to this section of unscientific combinations. In case of scientific drugs, there will be little scope for inflated pricing and wild claims of effectiveness. Hence, no scope for illegitimate profit.
iii. Curbing of irrational therapy: With irrational drugs missing, it is obvious that irrational prescribing will be curbed to a significant extent.
iv. The debate on generic name vs. brand name: This problem will cease to pose any difficulty or risk to the consumers. Even if multiple brand names of one and the same drug persist the consumer in any case receives scientific drugs i.e. every brand will contain, say, only amoxycillin and none with bromhexine or lactobacillus. Universal use of generic nameis, however, welcome.
v. Essential Drugs: The concept of Essential Drugs as advocated by WHO and adopted the world over will hereafter lose its special significance and importance. With only scientific drugs remaining in the market, all essential drugs will also be there.

Banning of Drugs

Certain unfortunate features in the banning exercise in India are:

1. Piece-meal approach: Instead screening all the formulations available in the market on the basis of effectiveness and safety, on the face of demands from different quarters including the drug activists, the government started examining only those formulations which contained drugs which were already banned abroad. In this exercise also, as we will see later, steps taken by the government were half-hearted, if not mischievous. A large majority of useless unscientific drugs (the so-called 'grand father drugs') were left out. These drugs were not considered because they were not banned by the countries abroad. However, the fact was that those drugs were not marketed or already removed by the manufacturers in those countries so that the question of banning did not arise in their case.
2. Incompetent bureaucracy: Government started banning drugs without ascertaining its legal authority to do so. The concerned bureaucracy either knew it or it was not aware of this lack of legal authority. Naturally, the initial ban order was challenged in the court of law by the manufacturers

and nullified by the court. Subsequently, the government could acquire the authority to ban drug(s) by ammending the existing Act by way of introducing new sections 10 (A) and (26A) in the Drugs and Cosmetics Act, 1940 and Rules, 1945.

3. Pro-industry Government: Another ridiculous aspect of the ban orders was banning with prospective effect i.e. drug companies concerned were asked to stop manufacturing the banned drugs after a certain period of the ban order and the sale of those banned drugs so manufactured would not be permitted six months to one year after the date of stoppage of manufacture. The situation may be compared with allowing an aircraft to fly a couple of flights with the knowledge that an explosive device has been implanted in to the aircraft. This pro-industry stance of the government was highlighted by the judges of the Kerala High Court with the observation that between loss of lives or money of the consumers and the loss of the drug companies would suffer, if the drugs were banned with immediate effect and the ban orders were circulated widely, government was more concerned for the latter.
4. Clandestine maneuvers: The original decision and recommendations of the statutory body like drugs consultative committee (DCC) was modified and for unexplained reasons several harmful drugs recommended by DCC for banning were ultimately given exemptions from the ban order by the bureaucracy. These include formulations of analgin, clioquinol, combinations of allopathic with Ayurvedic drugs, combinations of chloramphemicol with streptomycin, etc.
5. Pro-industry maneuver: Ban orders are published in generic name to help the drug companies to continue selling their banned products in the brand names with the apparently reasonable plea that their brand names have not been banned. When drug action groups published brand names of drugs which should come under the ban orders, drug companies resented and sent protest letters claiming that their brands were not banned and demanded publication of rejoinders to that effect.
6. Clever framing of the ban order: To help the drug companies ban orders are framed cleverly with ambiguities with a view to making them open to more than one interpretation, helping thereby the unscrupulous drug companies take advantage of the confusion and continue sale of banned drugs.
7. Suppression of information: Ban orders are not circulated even to the govt. agencies not to speak of govt. controlled mass media and the vast world of prescribers and sellers. This helps the drug companies to continue selling of the banned products for years after the promulgation of the order.
8. Not acting according to law: In our country there is no system of call back of the unsold banned drugs, The licences of the banned drugs are not

revoked. Moreover, the ban orders are not implemented by the authorities concerned. All these help the manufacturers of the banned drugs to exhaust their products over the years after the promulgation of the ban order.

9. Undemocratic practice: Requests by the drug acivists and other non-govt. organisations to help the government to propagate the ban orders among the prescribers and consumers are not even acknowledged or replied. There is every reason to believe that the authorities concerned want to keep the ban order secret so as to help the drug companies.
10. Collusion between the Government and the drug companies: Because of ambiguities in the ban orders or procedural lapses in issuing the orders or for no valid grounds certain drug companies frequently move the courts of law and easily obtain stay orders. The government does not contest the cases. The manufacture and sale of banned drugs are thus allowed to continue. This gives rise to the reasonable suspicion that the companies file the cases in collusion with the government.
11. Unauthorized action: Initially ban orders are cleverly framed in ambiguous language. Subsequently, taking help of the ambiguity Drugs controller of India gives exemption to several banned formulations according to his sweet will to help the drug companies notwithstanding the fact that he has no authority do so. Any amendment/modification of any gazette government order (like the ban orders) can only be done by notifying in the Gazette.

Drug Action

The impact of the campaign by the drug action groups for the last two decades definitely shows several positive trends. This may be evident from the following lessons.

1. Government had to for the first time openly admit in its policy declaration in 1986 that there exists many bannable drugs in the market and the government would take appropriate steps to weed out those drugs; to ensure that only good quality medicines are available in the market government would establish several quality control laboratories throughout the country; to record morbidity and mortality due to consumption of drugs the government would set up adverse drug reactions monitoring centres. Though very little or nothing has been done thereafter yet we should remember these were some of the important demand of the drug action groups and All India Drug Action Network (AIDAN) in particular.
2. Perhaps today many are not aware of the boycott campaign launched by the constituents of AIDAN to compel the manufacturers to remove banned drug (fixed dose combinations of chloramphenicol and streptomycin in particular). Due to adverse publicity in national as well as international publications several companies

conceded the demand and removed the banned drugs from the market/ withdrew court cases. The boycott was supported by a significant number of medical practitioners and an internal documents of the companies showed appreciable fall in the sales of the companies concerned.

3. Victory in the E-P cases (please see elsewhere in the document for details) is another achievement of the drug action groups. The campaigns by drug action groups had some success as evidenced by:
   a. many medical practitioners have become aware of the existence of banned and bannable drugs in the Indian market and are demanding the up-to-date list of banned drugs.
   b. they are regularly writing to BODHI (Bulletin On Drug & Health Information, a bimonthly for the medical practitioners published by Foundation for Health Action) to know the scientifically of drugs they prescribe.
   c. several practitioners themselves are writing to the drug companies demanding scientific and complete information on their products and showing resentment against absurd or unsubstantiated claims.

4. The effect of the efforts made by the non-government organisations on stopping prescription of banned/ useless drugs is though a positive one but quantitatively not significant.

5. All these positive aspects of the campaign as well as the lessons learnt therefrom it is suggested that in order to make an effective and significant impact on stoppage of sale of banned and unscientific drugs, our task is to induce the government to do it. In order to do that the pointed task of the drug action and other NGOs appears to expose the bureaucracy's collusive activities favouring the drug companies. Some future action plans may be:
   a. emphasis should be shifted to highlight the unholy alliance between the bureaucracy and the drug companies; the neglect by the government to educate the public on drugs; not helping the prescribers by way of making arrangements for dissemination of unbiased and objective information on drugs licensed in India and continued medical education (CME).
   b. to mobilize the parliamentarians and others to support the demands of the drug action groups and the consumers' Associations.
   c. to bring about necessary amendments of the Drugs and Cosmetics Act (1940).
   d. to bring out editions of Indian National Formulary in line with British National Formulary (BNF).

e. to file public interest litigation's whenever necessary.

It is evident from the lessons learnt from the past experience on banning exercise by the Government of India, the criteria of selection of banned and bannable drugs should be based on only one stand point i.e. a prescriber should not prescribe any drug formulation which he (she) has not read in a textbook or was taught in his/her curriculum of study because the very idea that prescribers should learn about a drug from the drug traders is simply repugnant. Hence, only those drugs which are taught or teachable to the medical students should be allowed licence for manufacture and sale. This means barring scientific drugs all other drugs should be banned. Advantages of having only scientific drugs in the market have already been mentioned in the foregoing. This means to bring about total re-registration (licensing) of all drugs on scientific basis as was done in the USA in the sixties. The so-called Ayurvedic drugs, non-ayurvedic herbal and indigenous drugs should not be allowed to be promoted to any allopathic practitioners. Because prescription of non-allopathic drugs by the practitioners of allopathic system without having training in the other systems, according to the judgement (1996) of the Hon'ble Supreme court should be considered as quackery and should be punished accordingly.

Source: Dr. P.K. Sarkar, Foundation for Health Action, Kolkata, 2004.

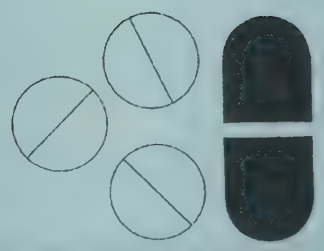
Drugs Banned But Still Sold

Fixed dose combinations of Salbutamol or any other bronchodilator with centrally acting anti-tussive and/or antihistamine. Following are some examples:

Brand Name	***Generic Name***	***Manufacturer***
Cadiphylate Elixir	**Theophylline,** Ephedrine, Guaiphenesin, *Chlorpheniramine*, Phenobarb, Aocohol	Zydus Alidac
Codoric Syrup	Codeine phosphate, **Ephedrine**, *Chlorpheniramine*	Euphoric
Noscof Tablet	*Diphenhydramine*, **Ephedrine**, Noscapine	Medicolabs
Protussa plus Syrup	Dextromethorphan, **Ephedrine**, *Chlorpheniramine*, Bromhexine	Knoll
B.I. Cough Syrup	*Chlorpheniramine*, Codeine, **Ephedrine**	Bengal Immunity
Bronolax Syrup	*Diphenhydramine*, Codeine, **Ephedrine**	Alkem
Wincuf plus	*Diphenhydramine*, **Ephedrine**, etc.	Wings

Drugs in **bold** letter is bronchodilator, *italic is antihistamine.*

Source: Dr. Gopal Dabade, Drug Action Forum, Karnataka, 2004.



10 Drugs of Doubtful Efficacy

Just a few examples are being given to highlight the need for unbiased information and need for restriction of drugs with little or no therapeutic value.

1. CEREBRAL VASOLIDATORS

Brand	*Manufacturer*
ARLIDIN (NYLIDRIN HCL)	U.S. VITAMIN
COMPLAMINA (XANTHINOL NICOTINATE)	GERMAN REMEDIES
CYCLASYN (CYCLANDALATE)	CIPLA
CYCLOSPASMOL (CYCLANDELATE)	ELDER
DUVADILAN (ISOXSURPINE HCL)	SOLVAY
FLEXITAL (PENTOXIFYLLINE)	SUN PHARMA
FLOWPENT (PENTOXIFYLLINE)	KNOLL
KINETAL 400 (PENTOXIFYLLINE)	PROTEC
MARTISPASMOL (CYCLANDELATE)	W. BUSHNEL
R.B. FLEX (PENTOXIFYLLINE)	TORRENT
OLDILAN – SR	OLCARE LAB
SEYDILAN (ISOXSURPINE)	SBP HEALTH CARE
TRENTAL & SR (PENTOXIFYLLINE)	AVENTIS

CEREBRAL ACTIVATORS do not have dilatory action on the cerebral arteries, these should be used with extreme caution in patients with severe obliterative coronary artery or cerebral vascular disease, since there is a possibility that these diseased areas may be compromised by vasodilatory effects of the drug elsewhere. Niacin may potentiate hypotensive drugs, phenothiazine derivatives and inactivate fibrinolysin.

Brand	*Manufacturer*
ARKACETAM (PIRACETAM)	RKG PHARMA
CERELOID (CODERGOCRINE)	SUN PHARMA
ENCEPHABOL (PYRITINOL)	MERCK
BILOVAS (GINKGO BILOBA)	GARMAN REMEDIES
GLUTANEUROL (L+GLUTAMIC ACID)	FRANCO INDIAN
HYDERGINE (CODERGOCRINE MEYSYLATE)	NOVARTIS
NEUROCETAM (PIRACETAM)	BROWN & BURK
NIMODIP (NIMODIPINE)	U.S. VITAMINS
NOOTROPIL 800 (PIRACETAM)	UNISEARCH
NORMABRAIN (PIRACETAM)	TORRENT
PIRATAB (PIRACETAM)	MARC LAB
SERMION (NICERGOLINE)	PHARMACIA
TRIVASTAT LA (PIRIBEDIL)	SERDIA
VASOTOP (NIMODIPINE)	PROTEC

Adequate data is not available to justify their use as cerebral activators.

2. APPETITIE STIMULANT (CYPROHEPTADINE & BUCLIZINE HCL) PAEDIATRIC FORM

Brand	Manufacturer	Brand	Manufacturer
Apilysin	Raymond	Dyprowal	Wallace
Aptagrow	Gracure Pharma	Decyp-P Syp & Drops	Alde Medi Impex
Appet	Apetiz Meridian	Dizest	DWD
Apetox	Kumaayun	G-1	Glyco Remedies
Apitol	Raymond	L-cetol	Mamta Pharma
Apectin L	Redson	L-cypro	Wilcure
Aptaup	Wings Pharma	Lecyp	East African (R)
Aptone	Mesco	Lycipep	Overseas Health Care
Apetamin	Tablets (Ind) Ltd	Lycyp	Brawn
Apetiz	Meridian Medicare	Mypon	Brooks Pharma
Apetone	Synokem	Normatone	Magnet Labs
Apilysin	Raymond	Peritol	Themis
Apitol Syp & Drops	Raymond	Practin	Merind
App-L	Vega Lab	Practin-En	Merind
Appet	Finecure	Pro App	Cure Quick Pharma
Apty	Cadex Labs	Proapt	Emson Medichem
Ciplactin	Cipla	Prodin Syp& Drops	Brickson
Cydine	CFL Pharma	Reboom	Pharma Tech Health Care
Cyp-L	Albert David	Seritol	Dew Drops Lab
Cypee	Comed Chemicals	Sorbex Plus	Excare Labs
Cypo	Shinto Organics	Stimulite G	Saga Lab
Cyaptin	Duckbill Drugs	Tricol	Cosmas Pharma
Cypon Syp & Drops	Geno	Juven	Vasphar (India)
Cypradin	Sivling Technologies		
Cyprovit	*Biocare*		
Cyprobit	Cubit Health Care		
Cylip oral	Dolphin		

Buclizine Hcl formulations: Longifene – UCB

These should not be used in newborn or premature infants. Overdosage particularly in infants and children may produce hallucinations, central nervous system depression, convulsions and death. May diminish mental alertness.

3. Digestive Enzymes

Digestants are drugs that supposedly promote the process of digestion in the gastrointestinal tract in conditions characterised by a lack of one or more of the specific substances that function in the digestion of food.While a number of products are marketed, including many bizarre mixtures of components, the only preparations that merit consideration are those of pancreatic enzymes.[1]

Since acid and peptic activity in the stomach can destroy the pancreatic enzymes, enteric-coated tablets are sometimes used. However the coating may prevent delivery of the enzymes in the duodenum.[2]

1. Goodman & Gilman 7th Edition, p. 989.

2. Goodman & Gilman 7th Edition p. 990.

Amylase is used in the production of pre-digested starchy foods and for conversion of starch into fermentable sugars in the brewing and fermentation industries. An alpha-amylase has also been suggested for use as an adjunct to standard therapy in the treatment of inflammation and oedema but is of unproven value.[3]

Pancreatin in given by mouth in conditions of pancreatic deficiency such as combizym (inner layer, pancreatic enzyme, outer layer amylase, cellulose, hemicellulose, and protease). Combizym compositum, cotazym B, Enzypan, Phazyme preparations containing pancreatin claimed to relieve discomfort caused by dietary imbalance, are of doubtful value.[4]

In most of the preparations given under, the concentration of amylase, papain, pepsin or pancreatin is very inadequate and most of them are not stable in acid medium. Particularly liquid enzymes, once reconstituted are not stable for more than 24-48 hours and as such are not rational.

Most of the enzymes viz. Diastase, fungal diastase are inactivated in the acidic medium of the stomach. These enzymes are hydrolysed when they come in contact with water. Hence all the liquid enzyme preparations become useless when reconstituted or when given in liquid form.

Brand	***Manufacturer***
Liquid oral (syrup) enzyme preparation	
AGLOZYME DROPS	AGLOWMED
ALFAZYME	ALFA PHARMA
AMINOZYME	STADMED
APEZYME	PANGEA PHARMA
ARISTOZYME DROPS	ARISTO
BESTOZYME	BIOLOGICAL EVANS
BESTOZYME PAEDIATRICS	BIOLOGICAL EVANS
BITAZYME	TRUE CARE
C-ZYME	D.P.P.L.
CATAZYME	STADMED
CATAZYME-P	STADMED
COZYME	CURE QUICK PHARMA
DEZYME DROPS	DEW DROPS LABS
DIGEASE	VERSATIL
DIGEPLEX	SHREYA
DIGEPLEX – DS	SHREYA
DIAGEST DROPS	HYGEIA PHARMA
DIGZYME	EMSON MEDICHEM
DIZYTONE	UNICHEM
DYSTASE	BROOKSPHARMA
ENCARMIN	ESKAG PHARMA
ENZ	GALPHA
FRUTIL	BUPA PHARMA
GENOZYME	GENO
LUPIZYME	LUPIN
LYCEROZYME	NATIONAL CHEM & PHARMA
MAPRAZYME	MAPRA
MARCOZYME	MARC LAB
MAXOZYME	BIPL (RADICO REMEDIES)
MEGAZYME DROPS	ADMAC PHARMA
MERIZYME DROPS	MERCURY
MOZYME	MOREISH PHARMA
MYLOZYME	SHINTO ORGANICS
NEO MERIZYME DROPS	MERCURY
NEOPEPTIN DROPS	RAPTAKOS
NITIZYME	WOODROCK
NOZYME	N.B. PHARMA
OBIZYME	ORNATE LABS
OSOZYME DROPS	OSHO PHARMA
PAPYTAZYME	A.F.D.
PEPZO	OSMED
PERKOZYME	PERK PHARMA
REMICARE DROPS	MERCURY HEALTH CARE
REMIZYME DROPS	MERCURY HEALTH CARE
RIVOZYME	EAST AFRICAN ®
SUZYME	SUZEN PHARMA
SYNZYM	SYNOKEM
TONOZYME	PHARMASYNTH
TRUZYME	MDC PHARMA
VITAPEP	DALLAS PHARMA
VITAZYME DROPS	EAST INDIA
VIVADASE	CACHET
VIZYLAC	UNICHEM

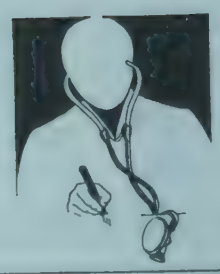
3. Martindale pp. 645.

4. BNF No. 5, 83, 62.

ZYMEX DROPS	MEDLEY
ZAIM DROPS	FINECURE PHARMA
ZYMONIT	SIGNIT LAB
ZYRUS	SIVLING TECHNOLOGIES

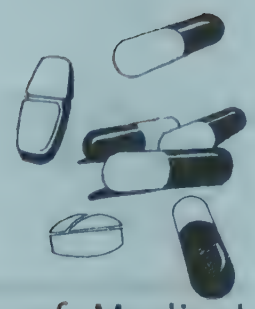
4. Clofibrate in Cardiology

In a large prospective study involving 5000 patients in a clofibrate treated group and 5000 in a placebo-treated group followed for an average of five years on drug or placebo and one year beyond, (the WHO study) there was a statistically significant 36% higher mortality due to noncardiovascular causes in the clofibrate-treated group than in a comparable placebo group. Both studies demonstrated that clofibrate users compared to nonusers have twice the risk of developing cholelithiasis[5] and cholecystitis[6] requiring surgery. Because of the hepatic tumorogenicity[7] of clofibrate in rodents (rats) and the possible increased risk of cholelithiasis, and because there is not substantial evidence of beneficial effect on cardiovascular mortality from clofibrate, this drug should not be used for the routine treatment of elevated blood lipids for the prevention of coronary heart disease.[8]



5. Cholelithiasis – stones in the gall bladder.
6. Cholecystitis – inflammation of the gall bladder.
7. Tumorogenicity – increased chances of developing tumors.
8. PDR: 1986 p. 613.

11 Attempts at Banning Hazardous Drugs



CASE STUDY I

HIGH DOSE EP DRUGS

The High Dose EP drugs have been commonly misused both as hormonal pregnancy tests and as early abortion agents. They contain very high doses of the hormone oestrogen and progesterone, which has a harmful effect on the foetus, especially during the first three months of pregnancy. As a pregnancy test, EP Drugs are not reliable, producing a false positive rate of 18 per cent. As an abortion agent, too, they are not effective. If a woman who takes these drugs for either purpose is in fact pregnant, there is a much higher risk that she will give birth to a deformed baby. It is because of this association of congenital malformation that the drug has been withdrawn in several countries and several companies have withdrawn their products.

On 8th March 1982 International Women's Day the E.P. Campaign was launched. The decision to do so was taken at a drug workshop, Low Cost Drugs and Rational Therapeutics held on 8-10 Jan. 1982 in Dr. Nobili College, Pune.

After a concerted campaign by consumers, health and women's groups who were part of All India Drug Action Network, facilitated by VHAI (amongst the organisations that played a major role in the E.P. campaign were ACASH, Arogya Dakshata Mandal, Medico Friends Circle, Drug Action Forum, West Bengal. Federation of Medical Representatives Association of India, Saheli Women's Forum and many many others), the Government of India finally banned EP drugs (12-48/79-D.O. June 21/22,1982). This was based on recommendations for the drug ban by Indian Council of Medical Research. Reasons given were as follows:

- Safer alternatives exist,
- The drug is grossly misused,
- The drug has been banned in several countries on grounds of safety.

Almost immediately, the pharmaceutical firms producing high dose EP drugs – Organon, for sometime renamed Infar (which produced menstrogen); Unichem (which produced the brand leader, EP Forte) and Nicholas which produced cyclenorm went to the courts in Kolkata and Mumbai respectively challenging the ban order not only on the grounds that their products were safe and essential but on the technicalities relating as to whether the Drug Controller of India or the State Drug Controller should be the authority to ban drugs, and that banning was a violation of their right to trade. Ironically, Menstrogen, a product of Infar (Organon) which challenged the ban order, was not even allowed to be registered in the parent country i.e. Netherlands.

EP case was a case of DOUBLE STANDARDS. 1983-Writ Petition was filed by Dr. Vincent Panikulangara in Supreme Court to

seek stoppage of sales of banned drugs. Dr. Vincent Panikuklangara's writ petition No. 3492 of 1983. In his application for hearing as amended on 7th February, 1983 under article 32 of the Constitution, he had asked the directions in public interest for the banning of import, manufacture, sale and distribution of such drugs which have been recommended for banning by the Drug Consultative Committee and he also asked for cancellation of all licenses authorising import, manufacture, sale and distribution in respect of such drugs. He also asked the Central Government to constitute a high power authority to go into the hazards suffered by the people of the country on account of such hazardous drugs being in circulation and to suggest remedial measures including award of compensations.

1986-November. Supreme Court ordered public hearings to give an opportunity for consumers and those affected to present their views and suggested 4 regional public hearings.

PUBLIC HEARINGS

1987-February, 5th – 1st public hearing was held in **Chennai**, (none of the consumer health and women's groups were informed and therefore none attended the first hearing. Ironically all industry representatives were present. The sole 'so called' consumer representative from an Organisation no one had ever heard of from **Mumbai***, asked for banning of all estrogen progesterone combinations including low dose combinations which are basically oral contraceptives. The hearings were for fixed dose combinations of high dose EP. This was seen by health groups as an effort to delegitimise consumer health and women's groups for being uninformed and making ridiculous demands. One of the consumer organisations was also infiltrated by one of the doctors representing the interest of one of the manufacturers of high dose EP, unknown to the health and consumer groups.

April 10th – 2nd public hearing was held in **Delhi**. There was heavy representation from the industry, office bearers of FOGSI and effort was made to make the Delhi hearing as the final hearing. Consumer and Health groups protested to this. Dr. W.V. Rane, Dr. Mira Shiva, Dr. C Sathyamala, Dr. S.G. Kabra made oral and written submission on behalf of consumer and health groups.

It was with months of preparation for 180 page submission with up-to-date information from experts like Dr. Isabel Gal who was the first to warn against the association of congenital malformation with high dose EP. It was with her efforts that led to 'out of court' settlement with the manufacturers and parents of the drug affected malformed children. Information from drug regulatory authorities that had banned the drug, and manufacturers that had withdrawn the drug, studies from

** 'Think, Tap, Press'*

within India had been painstakingly collected, compiled, analysed synthesized and made available to other drug action groups in other cities to prepare for the public hearings.

The industry was more than adequately represented, supported by a stream of office bearers of FOGSI, past and present Professors of Obstetric and Gynecology, authors of text books etc., to prevent the banning of the drug. The potential health hazard to the foetus was systematically denied, and the importance of the drug in the practice of obstetrics and gynecology was repeatedly emphasized.

A question was posed by Dr. Mira Shiva to the experts making pro EP drug submissions. How come that such senior people had left their private practice and flown from Mumbai, Kolkata etc., to get a banned drug unbanned because of their concern for the women of India, when unfortunately this concern was not reflected in demanding access to essential and life saving drugs in the rural areas and to the poor women to meet their reproductive health needs. An apology was demanded from her for "making insulting remarks against the profession". Apology was not given, inspite of this personal attack with pressure being put on the then Deputy Drug Controller convening the hearing to get apology on their behalf. The drug controller had been given magisterial powers by the Supreme Court to conduct these hearings.

Public meetings were organized in Kolkata to hold **public hearing** in Kolkata, followed by protest outside Organon manufacturer of Menstrogen (a EP brand). Repeated letters asking for Kolkata hearing were sent by anti-EP drug campaigners, as an effort to make Delhi hearing as the final hearing, was being made, under pressure, from vested interest.

July 10th –3rd public hearing was held in Kolkata, Dr. P.K. Sarkar, DAFWB, Amitava Guha, FMRAI, Dr. Mira Shiva, VHAI and others made submission.

The public hearing in Kolkata showed a bias against the consumer and health groups in terms of time given to make submission and also in terms of who was allowed to speak. During the hearing proceedings as tempers were raised and tension ran high, scuffle broke out between those for the ban and against the ban. Hearings were stopped and would have been scrapped had the consumer and health groups not pressed for continuation of the hearings. Knowing fully well that in its absence it would be the consumer concerns that would lose out.

July 14th – 4th public hearing was held in Mumbai, Dr. Raj Anand, ACASH, Mira Savara and many women's organization representatives made submissions. Other drug and health activists who had participated in previous hearings were also present for solidarity. Goons had been brought in to psychologically demoralize the women's groups and others demanding the ban. The only existing camera being used was snatched by the goons and camera roll exposed to prevent recording of their presence.

July 30th decision on High Dose EP drugs, six months extension asked for by the Drugs Controller of India, ICMR expert committee and DTAB consulted again, both recommended banning of the drug.

15th June 1988 through Gazette Notification No. 700E formulations of high dose EP banned.

30th June 1988 the public came to know of this ban through newspaper reports.

Efforts by consumer and health groups
Consumer and health groups requested the drug control authorities and Ministry of Information & Broadcasting:

- to get stocks of banned drugs withdrawn, to ensure that the names and brands of the manufactures are announced over AIR, Doordarshan, Newspapers and Magazines to warn chemists, doctors and consumers.

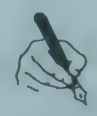
- to recommend to medical professional alternatives for pregnancy testing, rational management and secondary amenorrhoea etc.

- make low cost, safe, easy to use pregnancy tests available as part of mother and child health and for self-use by women.

On finding that high dose EP drugs even after being banned, were being sold freely, on 26th July 1988, the Association of Consumers Action for Safety (ACASH) filed Writ petition No. 4/27 of 1988 in Mumbai High Court, against the Commissioner of Food & Drug Administration of Maharashtra State to withdraw all stocks of these drugs, and warn the public of the brands of banned drugs.

Finding that the high dose EP injections continued to be sold, as an amendment it also asked for banning of injectable preparations along with tablets (which was expected & seemed obvious on looking at the Gazette Notification). The ambiguity of the wording in the Gazette Notification became obvious. So while the public going by the wording of the Preamble of the Gazette Notification and the newspaper reports, took it for granted that all formulations above the dosage mentioned were banned, while the manufacturers seemed well aware of the loophole of the ban, that injectables would be permitted. Why else would Unichem stop production of the tablets in April and continue manufacturing injections even after issuing of the ban order in June?

The Judgement



The following injectable preparations were mentioned in the Government counsel's submission. Existence of the latter two was not known to many.

Brand	***Manufacturer***
MENSTROGEN FORTE	INFAR (Organon)
E.P. FORTE	UNICHEM
CYCLENORM	HIGHLAND PHARMA
S.G. FORTE	SIGMA

It was obvious that in the absence of the list of the brands of banned drugs, (which was unavailable). It was impossible for the ban to be implemented. While on one hand there has been total unwillingness to accept a 'generics policy' and promote BRANDS in sales of drugs (as has been passed in the Philippines under Aquino) on the other hand, when it comes to **BANNING** sales of irrational hazardous drugs, there is total unwillingness to inform the public about the brands of banned drugs. Ironically, the banning of drugs has always been done with GENERIC NAMES.

High Court (Justice Lentin) stated that the **injectable** preparation will also remain banned till a convincing reason is given by the Drug Controller of India as to why they should not be also banned, along with the **tablets**. All stocks in Maharashtra were ordered to be withdrawn. Several chemist shops were raided. In September 1988, Drug Controller of India informed the other states about the Maharashtra High Court's judgement, about stalling production and sale of injectables till final judgement was given.

January 1989 Tablets and injectable preparations of high dose EP drugs continued to be sold in different parts of the country. Complaints had been made to both state and central drug control authorities.

It seemed an Expert Committee was again to be formed to review whether injectable preparations should be banned or not. After the public hearings and after the Gazette Notification, whether an Expert Committee was really needed, was a question that a large number of consumer and health groups were asking. If it took almost a decade to ban a single drug, how long would it take to remove other hazardous and irrational drugs?

The injectable preparation of EP drugs were ultimately banned. Due to absence of any form of post market surveillance system, sales of such drugs continue unrecognized or underestimated. Sales of Combinations like E.P. Forte (Ergot + Progesterone), D.P. Forte (Ayurvedic preparation) Oestrogen Progesterone, put separately but in the same drug pack have been reported.

There is a need for effective drug regulation, post marketing surveillance and consumer awareness, alertness and action, inclusion of Rational Drug Use in Medical Education Drug information helplines.

CASE STUDY II

1. **CHLORAMPHENICOL-STREPTOMYCIN**
2. **STEROID COMBINATIONS**

1979 Screening of 34 categories of fixed dose combination drugs took place.

1980 Fixed dose combinations of chloramphenicol and fixed dose combinations of steroids recommended for immediate withdrawal by the Drug Consultative Committee.

1981 From banning all fixed dose combination of steroids, the decisions was diluted to exclude

those combinations used for bronchial asthma. As expected, all fixed dose combinations of steroids changed their indications, to include bronchial asthma on paper, but their misuse for all conditions continued in reality.

1983 Gazette Notification issued banning fixed dose combinations of chloramphenicol (except chloramphenicol-streptomycin combination) and fixed dose combinations of steroid (except those used for bronchial asthma).

1986 Nation's New Drug Policy formulated. A sub-committee of the Drug Consultative Committee was formed to review the fixed dose combinations and weed out irrational and hazardous drugs. The sub-committee under the Chairmanship of Dr. M.A. Patel, Commissioner of Food and Drug Administrator, Gujarat recommended the withdrawal of chloramphenicol and streptomycin combinations.

3.11.88 Under Gazette Notification, fixed dose combinations of chloramphenicol-streptomycin and of steroid combinations (even for bronchial asthma) were banned.

1988 Stay orders against the ban on chloramphenicol-streptomycin combination was obtained by Lyka and Deys and by Roussel in the case of steroid combinations.

1988 Banned

February 1989: Whose responsibility is it to ensure that the Stay Orders against these bans are vacated at the earliest? Banned drugs are freely sold. No effort is made to inform chemists, doctors and consumers as to why these drugs were being banned.

Whose responsibility is it to inform the public that Chloramphenicol, while justified in typhoid, when used for trivial infections especially in childhood diarrhoeas, (most of which are viral) can prove hazardous? Even if efficacious, the safety factor is low to justify its use for trivial indications. It can cause bone marrow depression, agranulocytosis, (i.e. fall in white blood cell count) and even death with resultant infection due to decreased resistance.

Salmonella (i.e. microorganisms which cause typhoid) have in many places developed resistance to chloramphenicol, due to its misuse for indications where it is not rationally justified. Moreover the main treatment of diarrhoea (i.e. Oral rehydration is marginalised and such drugs masquerading as diarrhoea treatment and further hazard).

Where streptomycin in combination is concerned-when single ingredient streptomycin for TB patients is not available, its misuse in combination, (when safer and more effective alternatives exist) is not justified.

Whose responsibility is it to ensure that this pattern of obtaining Stay Orders routinely, even when potentially hazardous drugs are involved, are not granted?

Whose responsibility is it to ensure that manufacturers who continue to challenge drug control authorities and squeeze profits from the public are given deterrent punishment? In view of the failure of the Drugs and Cosmetics Act of 1940 and its amendment in 1982, and the Consumer Protection Bill of 1986 to protect the consumer, so far it is obvious that other measures need to be sought, besides making these acts more functional so as to safeguard the interest of the public.

In view of death or disability due to consumption of a banned drug who should be held accountable? The prescriber, the dispenser, the distributor, or the manufacturer? What should be the liability of the authorities responsible for weeding out irrational & hazardous drugs? Centre? State?

THE GAZETTE OF INDIA
EXTRAORDINARY
PART II-SECTION2 – SUB-SECTION (1)
PUBLISHED BY AUTHORITY
NEW DELHI, WEDNESDAY, JUNE 15, 1988 JYAISTHA 25, 1910

MINISTRY OF HEALTH & FAMILY WELFARE
NOTIFICATION
New Delhi, the 15th June, 1988

G.S.R. 700 (E). – Whereas the Central Government is satisfied that the use of high dose formulation of Oestrogen and Progesterone is likely to involve risk to human beings and such formulation have no therapeutic justification and it is necessary and expedient in the public interest so to do:

Now, therefore, in exercise of the powers conferred by section 26-A of the Drugs and Cosmetics Act. 1940 (23 of 1940), the Central Government hereby makes the following further amendment in the notification of the Government of India in the Ministry of Health and Family Welfare No. G.S.R. 578 (E), dated the 23rd July, 1983, namely:

In the Table appended to the said notification, after serial number 26 and the entries relating thereto the following serial number and entries shall be inserted namely:

"27 Fixed dose combination of Oestrogen and Progestin (other than oral contraceptives) containing per tablet estrogen content of more than 50 mcg. (Equivalent to Ethenyle Estradiol) and of progestin content of more than 3 mg (equivalent to Norethisterone Acetate).

[No. X-11018/1/88-DMS & PFA]
J. VASUDEVAN, Jt. Secy.

Note: Government of India Ministry of Health and Family Welfare Notification No. C.S.R. 578(E), dated 23-7-1983 was amended by the following notification published in the Gazette of India Extraordinary, Part II Section 3(i).

THE GAZETTE OF INDIA
EXTRAORDINARY
PART II – SECTION 3 –Sub-Section (i)
PUBLISHED BY AUTHORITY
NO. 575 NEW DELHI, THURSDAY, NOVEMBER 3, 1988/KARTIKA 12, 1910
MINISTRY OF HEALTH AND FAMILY WELFARE
New Delhi, the 3rd November, 1988

NOTIFICATION

G.S.R 1057 (E), - Whereas the Central Government is now satisfied that long term use of steroids in fixed dose combination drugs for treatment of asthma is likely to involve risk to human beings and such formulations do not have therapeutic justification:

And whereas the Central Government is now also satisfied that fixed dose combinations of chloramphenicol for internal use is likely to involve risk to human beings:

And, whereas the Central Government is satisfied that it is necessary and expedient in public interest to prohibit the manufacture and sale of the drugs aforesaid.

Now, therefore, in exercise of powers conferred by section 26A of the Drugs & Cosmetics Art, 1940 (234 of 1940) the Central Government hereby makes the following further amendments in the notification of the Government of India, in the Ministry of Health and Family Welfare No. G.S.R. 578(E), dated 23rd of July, 1983 namely:

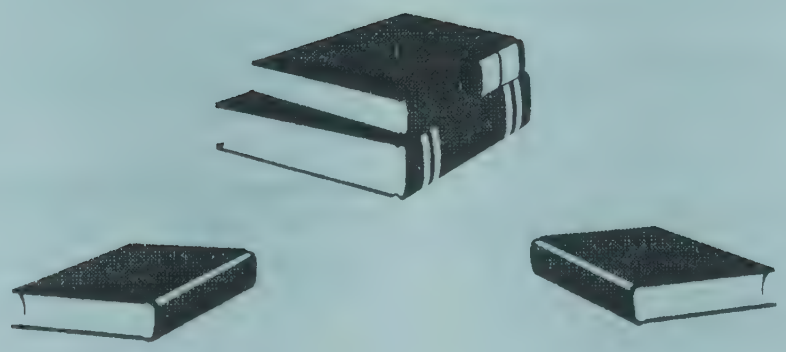
In the Table under the said notification for items 14 and 15 the following items shall be substituted namely:

"14. Fixed doses combination of corticosteroids with any other drug for internal use.
15. Fixed dose combinations to Chloramphenicol with any other drug for internal use."

[No. X-11014/2/88-DMS & PFAJ
SMT. VINEETA RAI, Jt. Secy.

Note: Government of India Ministry of Health & Family Welfare Notification No. G.S.R. 578(E), dated 23rd July 1983 was amended by the following notification published in the Gazette of India, Extraordinary, Part II, Section 3 (i) namely:-

1. G.S.R. 49 (E) dated 31.1. 1984.
2. G.S.R 322 (E), dated 3.5.1984.
3. G.S.R. 8634(E), dated 22.11. 1985.
4. G.S.R. 700 (E), dated 15.6. 1988.



12 Bangladesh Drug Policy

CRITERIA FOR WITHDRAWAL OF IRRATIONAL AND HAZARDOUS DRUGS

Bangladesh Drug Policy inspired by the Hathi Committee report and based on WHO's guidelines for Rational Drug Policy was the first policy in our region to be announced and implemented. It has survived regime changes and resistance from the pharma companies and has benefited its poor.

BANGLADESH DRUG POLICY

The Bangladesh Drug Policy of 1982 was aimed at:

1. ensuring production of essential and life saving drugs,
2. withdrawal of irrational and hazardous drugs,
3. ensuring quality control,
4. national saving by limiting imports to only essential and priority drugs,
5. ensuring affordability of the drugs by curtailing price increase.

Major Recommendations of the National Drug Policy

The National Drug Policy of Bangladesh was seen as an integral part of the National Health Policy – applicable not just for the **modern medical system** but also the **traditional system,** not just for the **public sector** but also the **private sector.**

The objective of the National Drug Policy was to rationalize procurement, production, quality control, distribution and drug pricing and bring it under a single legislative and administrative control. (Unlike in our country where loopholes between jurisdiction and accountability of drug policy matters between centre, state, Chemicals Ministry, Health Ministry and Commerce Ministry have never allowed rationalization of drug policy and seen repeated attempts sabotaged).

To ensure Rational Drug Use, there must be a rational drug policy. Bangladesh drug policy is a courageous example of such a policy.

BANNING OF DRUGS IN BANGLADESH

Finally, the drugs that were on the market were checked against the Guidelines resulting in a recommendation that 1,707 of them be withdrawn completely. The drugs to be banned were divided into three categories:

SCHEDULE ONE DRUGS: Regarded as harmful, these were to be forbidden from being made or imported **immediately** and withdrawn from sale within 3 month. The time delay was simply to collect and destroy the dangerous products.
Number affected: 305

SCHEDULE TWO DRUGS: These were medicines composed of combinations of similar or incompatible ingredients,

which did not enhance their therapeutic value and which carried the risk of increased toxicity as well as being deemed unnecessarily expensive. **Six months** were allowed for selling off existing stock and submitting new formulations.
Number affected: 134

SCHEDULE THREE DRUGS: These were either considered useless and unnecessary or were famous brand name products made under license. No royalties were to be paid overseas any more for the right to use such a name patented abroad. Any pharmaceutical company based in Bangladesh could make a similar drug without paying a license fee. All Schedule Three drugs were to be withdrawn within **nine months.**
Number affected: 1,268

Finally a list of drugs was drawn up by generic name for each level of the health system in the county. 12 essential drugs were for use in the village, an additional 33 for primary health care up to local health complex level (the small regional or town hospital and a complete list of 150 drugs for use in the regional and national hospitals. A supplementary list of 100 drugs was established for restricted use by specialists.

The Drug Control (Ordinance) was implemented on 12th June 1982, effectively putting into law the Expert Committee's recommendations, although prolonging the time allowed for implementation of the three schedules to six, nine and eighteen months respectively. A later review committee brought in amendments which reduced the banned list of drugs by 60. Despite subsequent internal and international pressure, General Ershad and his government stood firmly behind the new policy. The substance of the original recommendations continues to form the basis of the National Drug Policy of Bangladesh. It came into full operation in June 1984.

CRITERIA FOR WITHDRAWAL OF IRRATIONAL & HAZARDOUS DRUGS

The sixteen criteria Bangladesh used in 1982 to decide which drugs were useful and which should be banned:

1. The combination of an antibiotic with another antibiotic or antibiotics with corticosteriods or other active substances will be prohibited. Antibiotics harmful to children (e.g. tetracycline) will not be allowed to be manufactured in liquid form.
2. The combination of analgesics in any form is not allowed, as there is no therapeutic advantage and it only increase toxicity, especially in the case of kidney damage. The combination of analgesics with iron, vitamins or alcohol is also not allowed.
3. The use of codeine in any combination form is not allowed as it causes addiction.
4. In general no combination of drugs will be used unless there is absolutely

no alternative single drug available for treatment or if no alternative single drug is cost effective for the purpose.

Certain exceptions will be made in cases of eye, skin, respiratory and hemorrhoidal preparations, cotrimoxazole, oral rehydration salts, antimalarial, iron-folic, etc. as well as certain vitamin preparations, allowing combinations of more than one (1) active ingredient in a product.

5. Vitamins should be prepared as single ingredient products with the exception of B complex. Vitamins will not be allowed to be combined with any other ingredient such as minerals, glycerophosphate, etc. It will be allowed to produce vitamins in tablets, capsules and injectable form only. No liquid forms will be permitted because of wastage of financial resources and the tremendous misuse involved however, paediatric liquid multivitamin will be allowed to be manufactured in bottles of upto 15 ml. Size with droppers. Paediatric liquid preparations of single ingredient vitamins will also be allowed to be manufactured in bottles of up to 15 ml. with droppers.

6. No cough mixtures, throat lozenges, gripe water, alkalis, etc will be allowed to be manufactured or imported as these are of little therapeutic value and amount to great wastage of our meagre resources.

7. The sale of tonics, enzymes, mixtures/ preparations and so-called restorative products flourish on consumer ignorance. Most are habit-forming and with the exception of pancreatin and lactase, these are of no therapeutic value. Henceforth, local manufacture or importation of such products will be discontinued. However, pancreatin and lactase will be allowed to be manufactured and/or imported as single ingredient products.

8. Some drugs are being manufactured with only a slight difference in composition from another product but having similar action. This only confuses both patients and doctors. This will not be allowed.

9. Products of doubtful, little or no therapeutic value and rather sometimes harmful, and subject to misuse will be banned.

10. All prescription chemicals and galenical preparations not included in the latest edition of British Pharmacopoeia or British Pharmaceutical Codex will be prohibited.

11. Certain drugs, in spite of known serious side effects and possibility of misuse, having favourable risk-benefit ratio may be allowed to be produced in limited quantity for restricted use. These will be prescribed by specialists only.

12. The same or close substitute of a drug which is being produced in the country will not be allowed to be

imported as a measure of protection for the local industry. However, if local production is far short of needs, this condition may be relaxed in some individual cases.

13. A basic pharmaceutical raw material which is locally manufactured will be given protection by disallowing itself or its substitution to be imported unless sufficient quantity is not available in the country.

14. The role of multinationals in providing medicines for this country is acknowledged with appreciation. In view of the calibre of machinery and technical know how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will be solely with the national companies, leaving multinationals free to concentrate their effort and resources on those items not so easily produced by smaller national companies. Multinationals will, however, be allowed to produce injectable vitamins in single ingredient products.

15. No foreign brands will be allowed to be manufactured under license in any factory in Bangladesh if the same or similar products are available or manufactured in Bangladesh, as this leads to unnecessary high prices and payments should be reviewed.

16. No multinational company without their own factory I Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on toll basis.

After approval of these recommendations by Government, the licensing authority for drugs (Director, Drug Administration) will have to issue necessary orders withdrawing/cancelling the licensing/ registration of the products, with the provision of a maximum period of six months grace for using up the present stock of corresponding raw materials. Henceforth no raw materials should be allowed to be imported for the manufacture of these products. All future licensing/registration should be given after evaluation of the products on the basis of the above criteria.

Withdrawal of irrational and hazardous drugs cannot effectively take place in isolation, it has to be done in context of a Rational Drug Policy. Withdrawal off irrational and hazardous drugs and availability of essential and life saving drugs are Flip slides of the same can.

BANGLADESH

1. **A basic essential drug list** of 150 drugs established with 100 specialized drugs in the supplementary list.

   150 drugs for tertiary care
   45 drugs for primary health care
   12 drugs for village health workers

2. Use of **generic names** for manufacture and sale of the e45 primary care drugs.

3. Preparation and Publication of **National Drug Formulary.**
4. **Eliminate product patents** and limit use of process patents.
5. Revise 1940 Drugs Act to **include a registration system for Ayurvedic, Unani and Homeopathic medicines.**
6. **Enforcement of good manufacturing practices** (GMP) including adequate quality control.
7. **Control of labelling and advertising**
8. **Price Control**
9. **Prescription control of toxic poisonous** and habit **forming** drugs.
10. **Establishment of special drug courts and heavy penalties.**
11. **Regulation of technology transfer** and licensing agreements with foreign collaborators.
12. Restriction of ownership of retail pharmacies to professional pharmacists only.
13. Set up a **National Drug Control Lab** by 1995.
14. **Prevent TNC's from manufacturing simple products** like common analgesics, vitamins, antiacids.
15. Establish **registered retail pharmacies,** under the supervision of qualified pharmacists, at every government hospital. Strengthen the Drug Administration by training all Thana health administrators to act as drug inspectors.

In 1988 the **National Health Policy** which included integration of Health and Family Welfare decentralization of health programme to (Upazila) Block.

- **introduction of medical audit and registration of all health workers.**
- **Abolition of private practice for all teachers in government medical colleges** and postgraduate institutes and doctors upto the level of junior consultants.
- **Introduction of laws to ensure quality health care** and **compensation to person** who have suffered as a result of negligence by the medical profession.
- Introduction of various other legislative and administrative measure.

The above National Health Policy which was formulated in the interest of the Bangladesh's public could have been sabotaged with the Bangladesh Medical Association going on 72 hour strike, expulsion of 3 of the doctors involved in formulating this progressive Health Policy. One of the formulators being Dr. Zafrullah Chowdhury the Chief Architect of the Bangladesh Drug Policy, recipient of the Magasaysay Award.

IMPACT OF THE DRUG POLICY

10 years after the National Drug Policy of Bangladesh is in place results show that not merely the country but its people have also benefited.

The achievements are as follows:

1. **Increased production of Essential Drugs:** Essential Drug Production increased from 30% to 80% of total production 116 were identified as essential.
2. **Removal of irrational and hazardous drugs:** Over 1707 combination have been withdrawn.

While efforts towards getting irrational and hazardous drugs continue, our aim is improved health status and affordable rational health care services for our people specially the vulnerable and the marginalised which is not possible without implementations of rational drug and rational health policy.

It is in this context that the Bangladesh experience becomes important.

3. **Affordability of Drugs:** Decrease in Drug Prices

Drug price share decreased in a longer number of cases but if increased the increase has been marginal and the drug prices have statutized increasing only 20% as compared to 179% in the consumer price index.

4. **National Saving with Import Substitution:** Over $600 million dollar saving has taken place with abolition of transfer pricing, decreased dependency on imports and prioritization of imports to essential drugs.

5. **Increased local production:** Share of local production increased from 35 to 60% with overall production increasing by 217%.

6. **Quality Assurance:** Improvement in quality control resulted in proportion of substandard drugs decreasing from 36% to 91%.

7. **Rationalization of Prescription:** A rational drug policy is crucial in rationalizing drug prescription.

A study conducted in 1992 by International network for Rational Use of Drugs with Pharmacology and Community Medicine departments of 4 medical colleges assessed drug use pattern for six common diseases.

The study found:

- average number of drugs per prescription was – 1.4
- patients receiving drugs according to the prescriptions with adequate drug information was - 81%
- drugs selected from essential drug list – 85%
- prescription by generic names – 78%
- patients treated with antibiotics– 24.5%

In 1990 8th anniversary of National Drug Policy prescription of misused therapeutic groups of drugs e.g. Antibiotics, narcotics, hormones (except contraceptives) was found to have decreased substantially.

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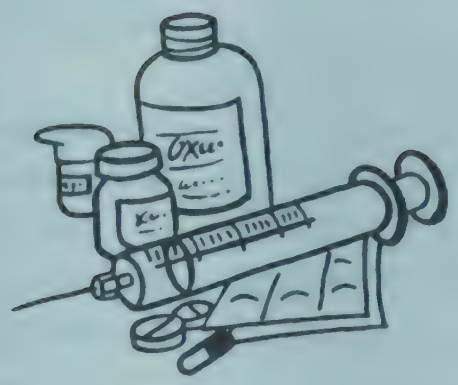

People have a

right to health
right to health care
right to essential medicines

13 Essential Drugs

Definition of Essential Medicines

Definition of Essential Medicines

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

(Ref: WHO Policy Perspectives on Medicines, March 2004).

A. CRITERIA FOR THE SELECTION OF ESSENTIAL DRUGS

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms.

The choice of such drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and genetic, demographic and environmental factors.

Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.

Each selected drug must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established.

Where two or more drugs appear to be similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price and availability.

In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost of the drug, must be considered. The cost/benefit ratio is a major consideration in the choice of some drugs for the list. In some cases the choice may also be influenced by other factors, such as comparative pharmacokinetic properties, or by local considerations such as the availability of facilities for manufacture or storage.

Most essential drugs should be formulated as single compounds. Fixed-ratio combination products are acceptable only

when the dosage of each ingredient meet the requirements of a defined population group and when the combination has a proven advantage over single compounds, administered separately, in therapeutic effect, safety or compliance.

GUIDELINES FOR ESTABLISHING A LIST OF ESSENTIAL DRUGS

Since the first report on the selection of essential drugs was published by WHO in 1977, the concept of essential drugs has been widely applied. It has provided a rational basis not only for drug procurement at rational basis not only for drug procurement at national level but also for establishing drug requirements at various levels within the health care system. In fact, many developing countries have already selected essential drugs according to their needs and the related programmes are, in some cases, at an advanced stage of implementation.

Taken from WHO's Technical Report Series No. 825, 1992

NATIONAL ESSENTIAL DRUG PROGRAM

In order to ensure that an essential drugs programme is adequately instituted at national level, several steps are recommended:

1. The establishment of a **list of essential drugs,** based on the recommendations of a committee, is the starting-point of the programme. The committee should include individuals competent in the fields of medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, cooperation from WHO could be sought.

2. **The international nonproprietary (generic) names** for drugs or pharmaceutical substances should be used whenever available, and prescribers should be provided with a cross-index of non-proprietary and proprietary names.

3. **Concise, accurate and comprehensive drug information** should be prepared to accompany the list of essential drugs.

4. **Quality,** including drug content, stability and bioavailability, should be assured through testing or regulation, as discussed in section 5. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the required specifications.

5. **Competent** health authorities should decide the **level of expertise required to prescribe individual drugs** or a group of drugs in a therapeutic category. Consideration should be given, in particular, to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with

less training could be responsible for maintenance therapy.

6. The success of the entire essential drug programme is dependent upon the **efficient administration of supply,** storage and distribution at every point from the manufacturer to the end-user. Government intervention may be necessary to ensure the availability of some drugs in the formulations listed and special arrangements may need to be instituted for the storage and distribution of drugs that have a short shelf life or require refrigeration.

7. **Efficient management of stocks is** necessary o eliminate waste and to ensure continuity of supplies. Procurement policy should be based upon detailed records of turnover. In some instances, drug utilization studies may contribute to a better understanding of the requirements.

8. **Research,** both clinical and pharmaceutical, is sometimes required to settle the choice of a particular drug product under local conditions. Facilities for such research must be provided.

9. **A national drug regulatory authority** should be established along the lines recommended in the guiding principles for small national drug regulatory authorities presented in Annexure 1. The authority should interact with other interested bodies, including organizations responsible for drug procurement in the public and private sectors and the committee referred to in item 1.

B. ADVANTAGES OF THE CONCEPT OF ESSENTIAL DRUGS

Preparing a rational list of essential/ restricted drugs has several advantages: medical, economic, social and administrative.

MEDICAL ADVANTAGES

- It is medically, therapeutically and scientifically sound, and it ensures rational use of drugs i.e. ensuring efficacy and safety.
- It limits the use of irrational and hazardous drugs and decreases the risks of latrogenisis i.e., drug and doctor induced problem.
- It improves the possibility of monitoring adverse drug reactions in patients.

ECONOMIC ADVANTAGES

- It is economically beneficial to the nation because it prevents wastage of scarce resources on non-essentials.
- The economies of scale achieved in the large production of priority essential drugs brings down their prices.
- It curtails the aggressive marketing of non-essential formulations.
- It is economically beneficial to the patient because it prevents wastage on irrational drugs and non-essentials.

SOCIAL ADVANTAGES

- It responds to the real health needs of the people.
- It facilitates the dissemination of

correct unbiased drug information about the drugs to health personnel, medical practitioners and consumers in general.

- It makes it imperative to draw up priorities to meet the most urgent needs of the people for essential health care.

ADMINISTRATIVE ADVANTAGES

- It is organizationally sound because it makes quality control easier because of the limited number of drugs to be monitored.
- In facilitates the streamlining of production, storage and distribution of drugs, because of the smaller number of drugs involved.
- It helps in clear identification of the drugs.
- It facilitates the fixing of prices as well as the revision/withdrawal of excise duties, sales tax etc.

1. Hathi Committee had drawn up a list of 116 drugs as essential drugs in 1975 i.e., before WHO's Essential drug list which was brought out in 1977. Since then 13th revised edition has been brought out.

2. International Consultation on Rational Selection of Drugs 1986 was organised by VHAI to influence the New Drug Policy towards making of Essential Drug List, a model graded essential drug list was drawn up.

3. The 1986 drug policy list of category I & II drugs have been formulated; Category I - Drugs for National Health Programme, Category II - Other Essential Drugs, these drug lists had more to do with price fixation than with ensuring adequate production of Essential Drugs. Kelkar Committee set up to formulate this list heard the submission of consumer and health groups, who put forward of category II drugs.

4. In 1988 in Siliguri in a Consultation organized by IOCU, CDMU, VHAI, AIDAN, another effort at drawing up graded essential drug list was made.

5. Need for uniform mark up to decrease profitability of non-essential irrational drugs and provide incentives for manufacturers of Category I drugs i.e., Drugs for National Health Programmes was expressed. These consumer and Health concerns were incorporated in Kelkar Committee Report.

6. The Ministry of Health brought out the Essential Drug List in 1996. Since then the Essential Drug List has been revised and brought out as National List of Essential Medicines in 2003. We are reproducing it in the appendix. Making of an essential drug list does not mean much, unless it is made an integral part of an essential drug policy e.g., Delhi State Drug Policy - TN Policy.

7. **The Delhi society on Rational Drug Use played a major catalyst role for the Delhi policy.** Independently Delhi State Government and Tamil Nadu State Government have formulated **Essential Drug Lists** for their institutions in the public sector.[1]

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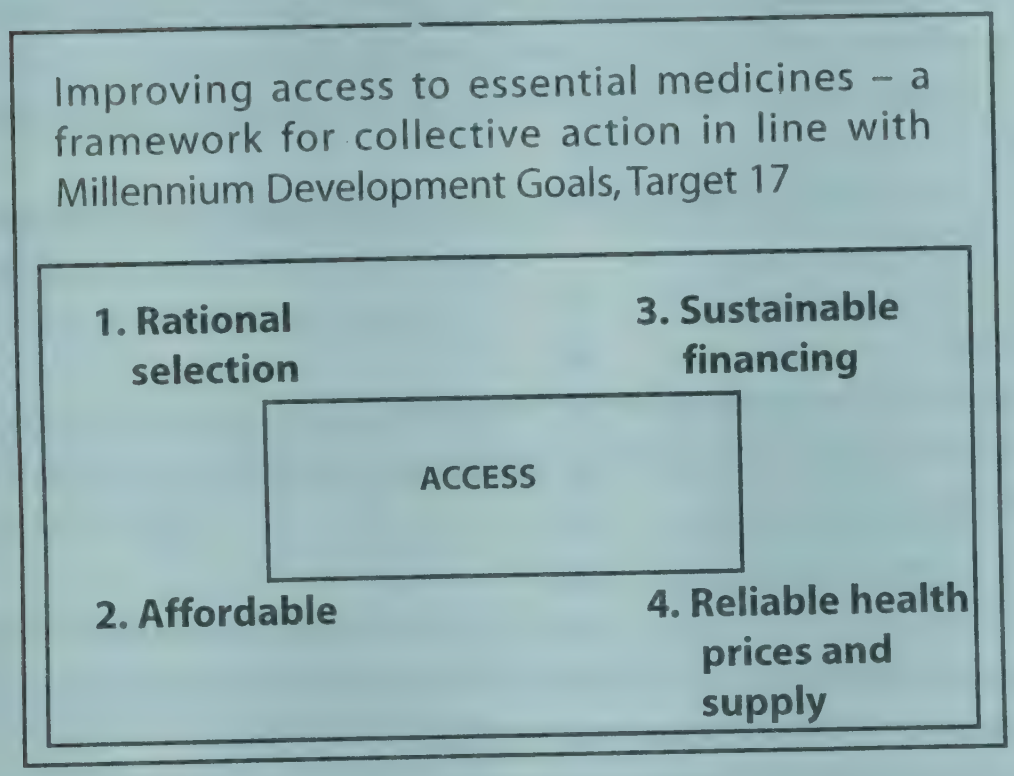
1. Rational Selection of Drugs, Dr. W.V. Rane, Dr. Mira Shiva, VHAI, 1986.

An essential drug policy ensures people's access to Essential Drugs



Access to medicines is supported by the principles of the essential medicines concept. Key points for policy makers:

- Common health problems for the majority of the population can be treated with a small number of carefully selected medicines;
- Individual health professionals routinely use fewer than 50 different medicines; the WHO Model List of Essential Medicines contains about 300 active substances;
- Training and clinical experience should focus on the proper use of these few medicines;
- Procurement, distribution and other supply activities can be carried out most efficiently for a limited number of pharmaceutical products;
- Patients can be better informed about the effective use of medicines by health professionals.

Ref.: Equitable Access to Essential Medicines: A Framework for Collective Action, WHO: Policy Perspective on Medicines, WHO, March 2004.

ACCESS TO ESSENTIAL MEDICINES

Key actions: check list for policy makers
Rational selection and use of essential medicines

- Develop national treatment guidelines based on the best available evidence concerning efficacy, safety, quality, and cost-effectiveness;
- Develop a national list of essential medicines based on national treatment guidelines;
- Use a national list of essential medicines for procurement, reimbursement, training, donations and supervision.

Affordable prices

- Use available and impartial price information;
- Allow price competition in the local market;
- Promote bulk procurement;
- Implement generics policies;
- Negotiate equitable pricing for newer essential medicines for priority diseases;
- Undertake price negotiation for newly registered essential medicines;
- Eliminate duties, tariffs and taxes on essential medicines;
- Reduce mark-ups through more efficient distribution and dispensing systems;
- Encourage local production of essential medicines of assured quality when appropriate and feasible;
- Include WTO/TRIPS compatible safeguards into national legislation and apply.

Sustainable financing

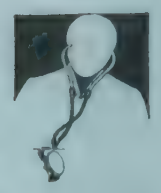
- Increase public funding for health, including for essential medicines;
- Reduce out-of-pocket spending, especially by the poor;
- Expand health insurance through national, local, and employer schemes;
- Target external funding – grants, loans, donations – at specific diseases with high public health impact;
- Explore other financing mechanisms, such as debt-relief and solidarity funds.

Reliable supply systems

- Integrate medicines in health sector development;
- Create efficient public-private-NGO mix approaches in supply delivery;
- Assure quality of medicines through regulatory control;
- Explore various purchasing schemes: procurement co-operates;
- Include traditional medicines in the health care provision.

Ref.: The Equitable Access to Essential Medicine: A Framework for Collective Action, WHO: Policy Perspective on Medicines, March 2004, WHO.

14 Delhi State Essential Drug Policy



The Delhi State Essential Drug Policy was initiated in 1994 with the efforts of Delhi Society for Promotion of Rational drug Use and the Delhi State Government.

The State Drug Policy was based on the well-accepted principles of Rational Drug Policy and clearly articulated by WHO.

The state Drug Policy was applicable for the Government Institutions in Delhi under the Delhi State government.

The Essential Drug List

The medicines used were those included in the Essential Drug List. The formulating of essential drugs was an exercise undertaken involving the doctors with discussions on the advantages of an essential drug list.

In the process, Graded Essential Drug List were brought out for different levels of health expertise and health institutions e.g. some drugs were for primary level, some for secondary, tertiary level.

Delhi State Drug Formulary and standard treatment guidelines **were made with information on drugs, their dosages, side-effects special precautions adverse drug reactions etc. standard treatment guidelines giving indications for which the drugs were to be used. Sensitization of doctors involved effectively communicating the principles of rational drug use.**

The evaluation of the exercise showed improvement in Drug Prescription Practice.

To make the above happen very comprehensive exercise was undertaken, constituting of:

- *double envelop tender system,*
- *drug procurement,*
- *bulk purchase,*
- *drug storage,*
- *inventory control,*
- *quality assurance*

This was possible since the state government was headed by a medical doctor – Dr Harshvardhan, who was convinced by the importance of this initiative provided the political backing. Such an initiative without the political will is not possible.

The result was that more essential drugs were made available for longer periods in more institutions. The state govt. by making bulk purchase made substantial savings in financial terms, using that saved money for more purchase of essential drugs.

Savings were also made as no non-essential irrational drugs were purchased. Streamlined procurement, storage and distribution resulted in continuous supply of drugs with out interruptions. Monitoring was easier as systems were known bringing in greater transparency and preventing any underhand dealings.

Since drug quality assurance was an important part of the exercise – besides the cost aspect – better quality of drugs were made available.

The Delhi State Drug Policy has continued inspite of change of the state government for which credit must be given to both the State Govts. those who initiated it and those who have continued to keep it in place, and did not dismantle it as happens with many schemes and projects.

As Dr. Harshvardhan had observed that earlier there were complaints that drugs were not available. Other complaints were related to the quality of drugs, their procurement and distribution and the information given to patients about the use of drugs. Each hospital had its own list of drugs, medicines came to hospitals in many different brand names, supply was erratic and the prescribing very often, unrestrained. "Though 30-35% budget of hospitals was spent on medicines, chronic shortages existed. Within 4 years of Delhi Essential drug Policy implementation effective and safe drugs became available, 90% of these drugs were absolutely essential".

The beneficiaries were 4 million 'outpatients' coming to OPDs annually and 'in patients' occupying the 4000 beds of the 2 state hospitals 15 smaller hospitals and 158 health centres.

The essential drug list

The list was formulated by a high power committee with well-informed experienced members.

Common list of 250 essential drug list was formed another list of 100 drugs for smaller hospitals was made. The 1st list formulated in 1994 had 329 drugs in 28 different categories based on WHO guidelines. Separate lists for indoor and out door patients were made Drugs for dental care and those used by specialists.

Main elements of the Drug Policy of the National Capital Territory of Delhi are the following:

1. All the essential drugs needed for health care should be available at all times at all the health facilities for the state. These drugs should be safe, effective and of good quality.
2. The facilities and manpower needed for providing a good, continuing quality control and assurance system of the drugs being used will be strengthened.
3. The system of procurement, storage and distribution of drugs will be modified to ensure that drugs of good quality, obtained at competitive prices are always available at the health units.
4. Rational use of drugs will be promoted. Rational use of the most appropriate drug prescribed at the correct dose, for the correct length of time. Medicines will be prescribed and ensuring as far as possible that appropriate drugs only are prescribed.
5. Doctors at all public health facilities will be encouraged to prescribe drugs by their generic names. Procurement of drugs will also be by generic names.
6. There will be strengthening of the health education programmes of the

government specially relating to drugs. This would promote rational use of drugs and enhance compliance. There would also be an acceleration of the continuing education programmes for doctors and para professional personnel in the field of drugs. This would include establishment of a drug information centre and development of links with non-governmental organization.

7. Research on all aspects of use of drugs will be an integral part of the drug policy in the state so that these results would be continuously utilized to modify the different components of the programme for the benefit of the people. Information will be collected to understand strengths and weaknesses of the present system and the impact of interventions.

The seven components of the drug policy are:

1. availability of safe and effective drugs
2. good quality control and assurance system
3. improved procurement storage and distribution system
4. rational prescribing of medicines
5. prescribing by generic names
6. strengthening of health education programme
7. research on all aspects of drug use

Steps taken for implementation of the drug policy

1. Selection of a list of essential drugs.
2. Pooled procurement of drugs for all hospitals in Delhi State.
   Establishment of a central drug procurement, strograge and distribution centre.
3. Preparation of Delhi State Drug Formulary.
4. Quality assurance :
   - Strengthening of drug inspectorate unit
   - Strengthening of quality control lab
   - Establishment of an efficient system of withdrawal of substandard products
5. Training in Rational Drug Use.
6. Provision of unbiased information on rational drug use. Setting up computerized drug information centre.
7. Preparation of standard treatment schedules for drugs use din primary health Centres at outpatient departments of hospitals.
8. Drug advertising and promotion setting up of ethical criteria for drug promotion and advertising.
9. Research on different aspects specially :
   - Drug expenditure
   - Drug utilization
10. Monitoring and evaluation setting up of 3 standing committees.
    - for selection of drugs
    - for drug procurement and stores management
    - for preparing drug formulary

Results of the Rational Use of Drugs (RUD) Programme

Drug prices contained over the years (see box I).

Drugs can be purchased at 35% cheaper rates with pooled procurement (see box 2).

90% of prescribed drugs are from list of essential medicines.

By use of standard treatment guidelines additional savings made.
Quality of drugs distributed in govt. hospitals ensured (earlier due to lowest tender purchase this was considered a problem area).
Drug prescription quality has improved not more than 3 drugs are prescribed.
Curtailing over prescription.

The Delhi State Drug Policy has been hailed as an exemplary model drug policy by WHO. Similar initiatives in other states are being promoted.

Delhi drug policy is mainly an essential drug policy focussing on availability of essential drugs by pooled procurement of good quality in the government hospitals. If the drug policy could be implemented also in the private sector it would be great, unfortunately regulation of the private sector – specially where rationally of drug prescription is concerned it has not been easy.

DRUG COSTS IN DELHI GOVT HOSPITALS

Name of Drug	Pooled procurement Rate	
	1993	2002
Capampicillin (500mg)	Rs.21.50 per10	Rs.13.83 per 10
Cap Ciprofloxacin(500mg)	Rs.24.30 per 10	Rs.9.48 per 10
Inj. Ceftazidine (1gm)	Rs.214 per vial	Rs.62.15 per vial
Inj. Streptokinase 15mu	Rs.1770.00Per inj.	Rs 885.00Per inj.

Ref: Rational Drug Use a programme of the Delhi Society for Promotion of Rational Use of Drugs.

COST ADVANTAGE IN SUPPLY OF ESSENTIAL DRUGS BY POOLED PROCUREMENT

Drugs	Open Tender	Pooled Procurement	% cost reduction
Syrup Amoxycillin	14.65	7.50	50
Tab Erythromycin	3.24	1.54	50
Tab Atenolol (50mg)	0.42	0.17	60
Inj. Ranitidine	1.87	1.63	12.50
Inj. Diazepam	5.53	0.93	80

Ref.: Rational Drug use a programme of the Delhi Society for Promotion of Rational Use of Drugs.

CRITERIA FOR EVALUATION OF TENDERERS' SHORTLISTING

1. The tenderer should have been in the manufacturing of drugs for a minimum of three years.
2. The tenderer should not have been blacklisted by any Government Procurement Agency.
3. The tenderer should not have been convicted under the Drugs and Cosmetics Act for manufacturing sub-standard or spurious drugs.
4. There should not be any case pending against the tenderer under the Drugs & Cosmetics Act for manufacturing spurious drugs.
5. The tenderers should have adequate manufacturing and quality control facilities.
6. The tenderers should have been following GMPs as laid down under schedule M to the Drugs & Cosmetics Rules, or as recommended by WHO.
7. The tenderers should have the services of at least one approved manufacturing chemist, and one approved Quality Control Chemist.
8. If the drugs have been recalled by the tenderers for quality defects during the last three years, he should not be considered for those drugs, unless the tederer has demonstrated that after recall he has taken corrective measurers and has studied the product for stability, and has developed a stability profile of that drugs.
9. The tenderers should be in a sound financial position.
10. The tenderers should have an annual turnover of Rs.12 crores or more.

15 Drugs and Legislations

THE CONSTITUTION OF INDIA

PREMABLE

WE, THE PEOPLE OF INDIA HAVING SOLEMNLY RESOLVED TO CONSTITUTE INDIA INTO A SOVEREIGN SOCIALIST SECULAR DEMOCRATIC REPUBLIC AND TO ALL ITS CITIZENS.

JUSTICE, SOCIAL, ECONOMIC AND POLITICAL, LIBERTY OF THOUGHT, EXPRESSION, BELIEF, FAITH AND WORSHIP; EQUALITY OF STATUS AND OF OPPORTUNITY AND TO PROMOTE AMONG THEM ALL.

FRATERNITY ASSURING THE DIGNITY OF THE INDIVIDUAL AND THE UNITY AND INTEGRITY OF THE NATION.

IN OUR CONSTITUENT ASSEMBLY
THIS TWENTY SIXTH DAY OF NOVEMBER 1949 DO HEREBY ADOPT, ENACT AND GIVE TO OURSELVES THIS CONSTITUTION.

CONSTITUTION OF INDIA

DUTY OF THE STATE TO RAISE THE LEVEL OF NUTRITION AND THE STANDARD OF LIVING AND TO IMPROVE PUBLIC HEALTH.

THE STATE SHALL REGARD THE RAISING OF THE LEVEL OF NUTRITION AND THE STANDARD OF LIVING OF ITS PEOPLE AND **THE IMPROVEMENT OF PUBLIC HEALTH** AS AMONG ITS PRIMARY DUTIES AND IN PARTICULAR, THE **STATE SHALL ENDEAVOR TO BRING ABOUT PROHIBITION OF THE CONSUMPTION EXCEPT FOR MEDICAL PURPOSES OF INTOXICATING DRINKS AND OF DRUGS WHICH ARE INJURIOUS TO HEALTH.**

THE DRUGS AND COSMETICS ACT 1940

The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Act Amendment 1982, are the main drug legislation's that are supposed to provide some form of control over the manufacture and sales of drugs.

The Drug Controller of India has the powers to prohibit manufacture of drugs which are not in public interest.

26A. POWER OF CENTRAL GOVERNMENT TO PROHIBIT MANUFACTURER ETC. OF DRUG AND COSMETIC IN PUBLIC INTEREST

Without prejudice to any other provision contained in this chapter if the central government is satisfied, that the use of any drug or cosmetics is likely to involve any risk to human beings or animals, or that any drug does not have the therapeutic value claimed, or purported to be claimed for it or contained ingredients and in such quantity for which there is no therapeutic justification and that in the public interest

it is necessary or expedient so to do then the government may, by notification in the official gazette prohibit the manufacture, sale and distribution of such drug or cosmetic.

28B. PENALTY FOR MANUFACTURE ETC. OR DRUGS OR COSMETICS IN CONTRAVENTION OF SECTION 26A

Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetics in contravention of the provisions of any notification issued under section 26a, shall be punishable with imprisonment for a term which may extend to 3 years and shall also be liable to fine which may extend to Rs. 5000.

30. PENALTY FOR SUBSEQUENT OFFENCES

a. Whoever having been convinced of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 6 years and with fine which shall not be less than Rs. 10,000. Provided that the court, may for any judgement impose a sentence of imprisonment for a term of less than 2 years and of fine of less than Rs. 10,000.

b. Under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 6 years but which may extend to 10 years and with fine which shall not be less than Rs. 10,000.

c. Under clause (d) of section 27 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 4 years or with fine which shall not be less than Rs. 5000 or with both.

d. Under clause (b) of section 27 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which may extend to 10 years or with fine or with both.

CONFISCATION

COGNIZANCE OF OFFENCES

No prosecution under this chapter shall be instituted except by an inspector.

33. POWER OF CENTRAL GOVERNMENT TO MAKE RULES

POWER TO GIVE DIRECTIONS

The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule made there under.

(1) The Central Government may after consultation with, or on the

recommendation of the Board and after previous publication by notification in the official gazette make rule for the purpose of giving effect to the provision of the chapter.

COMMENTS ON SECTION 33e

The Act of possessing a contraband or a prohibited article constitutes a continuing offence. A dealer could not possess such drugs during any period following the date of the issue of Notification and there after (Subhash Chander VS State of Punjab and others AIR 1989 P and H 238).

COMMENT ON SECTION 239

If a dealer is found selling, stocking or exhibiting for sale the prohibited drugs, an Inspector appointed under this Section can prosecute him by filing a complaint to the court who may in turn punish him (Subash Chander VS State of Punjab and others, AIR 1979 P and H 238).

THE DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENT) ACT OF 1954

The Act is meant to control the advertisements regarding drugs. It prohibits the advertising of remedies alleged to possess magic qualities and to provide for matters connected here with.

The Drugs and Magic Remedies Act prohibits a person, from taking part in the publication of any advertisement referring to any drug which suggests the use of the drug for:

a. procurement of miscarriage of women, or prevention of conception in women.
b. maintenance or improvement of the capacity of human being for sexual pleasure.
c. the correction of menstrual disorder in women.
d. the diagnosis, cure, mitigation, treatment or prevention of any venereal disease.

It is prohibited to directly or indirectly give a false impression regarding the true character of a drug or make false claim for it or to convey any false or misleading information in any material particular about it.

No person shall import into or export from India any document containing an advertisement of this nature.

Whoever contravenes the provisions of this Act shall, or connection, be punishable with imprisonment which may extend to 6 moths, with or without fine.

In case of subsequent corrections the imprisonment can be extended to one year. The document, article or thing which contains the offending advertisement can be seized and confiscated.

If the person contravening any of the provisions of the Act is a company every person who at the time the offence was committed was in charge of the business of the company shall be deemed guilty.

The prohibition under the Act does not apply to:

a. any sign board or notice displayed by registered medical practitioner
b. including the treatment of any disease, any treatise or book dealing with any of the matter from a bonafide scientific standpoint
c. any advertisement relating to any chemists for distribution among registered medical practitioner or to a hospital or laboratory and government advertisements

Source: The Indian Pharmaceutical Guide 1997, p. 15-24.

THE CONSUMER PROTECTION ACT, 1986

Objectives of the ACT

The Consumer Protection Act, 1986 (68 of 1986) is a milestone in the history of socio-economic legislation in the country. It is one of the most progressive and comprehensive piece of legislation enacted for the protection of consumers. The new law has been enacted after in-depth study of consumer protection laws and arrangements in the U.K., U.S.A., Australia and New Zealand. Before its formulation, consultations with representatives of consumer's trade and industry were also considered in a number of inter-ministerial meetings within the Government.

The main objective of the new law is to provide for the better protection of the consumers. Unlike existing laws, which are punitive or preventive in nature, the provisions of this ACT are compensatory in nature. The Act intends to provide simple speedy and extensive redressal to the consumer's grievances. For this purpose the Act envisages a three-tier quasi-judicial machinery at the national, state and district levels. The Act enshrines certain rights of the consumers and provides for the setting up of Consumer Protection Councils in the centre and the states. The objective of these Consumer Protection Councils will be to promote and protect the rights of the consumers.

Extent and Coverage of the Act

The salient features of the Act are summed up an under:

- The Act applies to all goods and services unless specifically exempted by the Central Government.
- It covers all the sectors whether private, public or cooperative.
- The provisions of the Act are compensatory in nature.
- It enshrines the following rights of the consumers:
  - (i) the right to be protected against the marketing of goods which are hazardous to life and property;
  - (ii) the right to be informed about the quality, quantity, potency, purity, standard and price of goods so as to protect the consumer against unfair trade practices;
  - (iii) the right to be assured, wherever possible, access to a variety of goods at competitive prices;
  - (iv) the right to be heard and too be assured that consumers' interests

will receive due consideration at appropriate forums;

(v) the right to seek redressal against unfair trade practices or unscrupulous exploitation of consumers; and

(vi) the right to consumer education.

- The Act envisages establishment of Consumer Protection Councils at the central and state levels whose main object will be to promote and protect the rights of the consumers.

- To provide simple, speedy and inexpensive redressal of consumer grievance, the Act envisages a three-tier quasi-judicial machinery at the national, state and district levels. At the national level, there will be a National Consumer Disputes Redressal Commission (to be known as the 'National Commission'). At the state level, there will be Consumer Disputes Redressal Commissions (to be known as 'State Commission') and at the District level, there will be Consumer Disputes Redressal Forums (to be known as 'District Forums'.

- The provisions of this Act are in addition to and not in derogation of the provision of any other law for the time being in force.

Who is a consumer?

All of us are consumers of goods and services. The producers of some goods and services also consume various other goods and services produced by others. In the Consumer Protection Act, the word 'Consumer' has been defined separately for the purpose of goods and services.

- For the purpose of goods, a consumer means a person belonging to the following categories:
  (i) One who buys any goods for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment;
  (ii) It includes any user of such goods other than the person who actually buys goods and such use is made with the approval of the purchaser.

For the purpose of services, a consumer means a person belonging to the following categories:

(i) One who hires any service or services for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment;

(ii) It includes any beneficiary of such service other than the one who actually hires the service for consideration and such services are availed with the approval of such person.

Who can file a complaint?

- A consumer
- Any voluntary consumer organisation, registered under the Societies Registration Act 1860 or the Companies Act, 1956 or under any other law for the time being in force.
- The Central Government
- The State Governments or Union Territory Administrations.

What constitutes a complaint?

Under the Act, a complaint means any allegation in writing made by a complainant in regard to one or more of the following:

- That he has suffered loss or damage as a result of any unfair trade practices adopted by any trader.
- That the goods mentioned in the complaint suffer from one or more defects.
- That services mentioned in the complaint suffer from deficiencies in any respect.
- That a trader has charged for the goods mentioned in the complaint, a price in excess of the price:
  - (i) fixed by or under any law for the time being in force; or
  - (ii) displayed on goods;
  - (iii) displayed on any packet containing such goods.
- The definition of 'goods', 'services' and 'unfair trade practices', 'defect' and 'deficiencies' are given in the Annexure – I.

Where to file a complaint?

- If the cost of the goods or services and compensation asked for, is less than rupees one lakh, then the complaint can be filed in the District Forum which has been notified by the State Government for the district where the cause of action has arisen or where the opposite party resides.

- If the cost of the goods or services and compensation asked for is more than rupees one lakh but less than rupees ten lakhs, the complaint can be filed before the State Commission notified by the State Government or the Union Territory concerned.

- If the cost of goods or services and compensation asked for, exceeds rupees ten lakhs, the complaint can be filed before the National Commission at New Delhi.

How to file a complaint?

Procedures for filing complaints and seeking redressal are simple and speedy.

- There is no fee for filling a complaint before the District Forum, the State Commission or the National Commission.
- The complainant or his authorised agent can present the complaint in person.
- The complaint can be sent by post to the appropriate Forum/Commission.
- A complaint should contain the following information:
  - a) the name, description and the address of the complainant;
  - b) the name, description and address of the opposite party or parties, as the case may be, as far as they can be ascertained;
  - c) the facts relating to complaint and when and where it arose;
  - d) documents, if any, in support of the allegations contained in the complaint;
  - e) the relief which the complainant is seeking.
- The complaint should be signed by

the complainant or his authorised agent.

Relief available to consumers

Depending on the nature of relief sought by the consumer and facts, the Redressal Forums may give orders for one or more of the following reliefs:

(a) removal of defects from the goods;
(b) replacement of the goods;
(c) refund of the price paid; or
(d) award of compensation for the loss or injury suffered.

Procedure for filing the appeal

- Appeal against the decision of a **District Forum** can be filed before the State Commission within a period of thirty days. Appeal against the decision of a **State Commission** can be filed before the National Commission within thirty days. Appeal against the orders of the **National Commission** can be filed before the **Supreme Court** within a period of thirty days.

- There is **no fee** for filing appeal before the State Commission or the National Commission.

- Procedure for filing the **appeal** is the same as that of complaint, except that the application should be accompanied by the orders of the District Forum/State Commission as the case may be and reasons for filing the appeal should be specified.

The limit for deciding complaint/ appeal

The thrust of the act is to provide simple, speedy and inexpensive redressal to consumer grievances. To ensure speedy disposal of consumer grievance, the following provisions have been incorporated in the Act and the rules framed thereunder:

- It is obligatory on the complainant of appellant or their authorised agents and the opposite parties to appear before the Forum/ Commission on the date of hearing or any other date to which hearing could be adjourned.

- The National Commission, State Commission and District Forums are required to decide complaints, as far as possible, within a period of three months from the date of notice received by the opposite party where complaint does not require analysis or testing of the commodities and within five months if it requires analysis or testing of commodities.

- The National Commission and State Commissions are required to decide the appeal, as far as possible, within 90 days from the first date of hearing.

Definitions

(i) "goods" means goods as defined in the Sale of Goods Act, 1930 (3 of 1930).
(ii) "service" means service of any description which is made available

to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, entertainment, amusement or the purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service;

(iii) the expression "unfair trade practice" shall have the same meaning as in section 36A of the Monopolies and Restrictive Trade Practices Act, 1969, but shall not include an unfair trade practice adopted by the owner of an undertaking to which Part A of Chapter III of that Act applies or by any person acting on behalf of, or for the benefit of, such owner.

(iv) "defect" means any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force or as is claimed by the trader in any manner whatsoever in relation to any goods.

(v) "deficiency" means any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance which is required to be maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service.

16 Quality Control

WHO & QUALITY ASSURANCE

Quality assurance of drugs, as embodied in good manufacturing practice and subsequent monitoring of quality throughout the distribution chain to utilization, is a crucial element in any essential drug programme. All aspects of these procedures have been dealt with at length in the twenty-sixth to thirty-first reports of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

Priority should be given to ensuring that the available drugs have been made according to good manufacturing practices and are of generally recognized quality. This requires knowledge of and confidence in the origin of the product. The risks of procuring drugs from anonymous sources cannot be overstressed. It is recommended that drugs are purchased directly from known manufactures, their duly accredited agents, or recognized international agencies known to apply high standards in selecting their suppliers.

Developing countries with inadequate laboratory facilities for drug analysis may by unable to carry out the process of quality control. In this connection, the Committee would emphasize the importance of WHO's certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. This has been available since 1975 as a means of exchanging information between regulatory authorities in importing and exporting countries. Its purpose are:

1. To provide assurance that a given product has been authorized to be placed on the market in the exporting country and, if not, to explain why authorization has been withheld.

2. To provide assurance that the plant in which the product is manufactured is subject to inspections at suitable intervals and conforms to the requirements for good practices in the manufacture and quality control of drugs, as recommended by WHO.

3. To provide for exchange of information on the implementation of inspections and controls by the authorities in the exporting country. In the case of serious quality defects inquiries may also be made.

In 1988 the scope of the certification scheme was extended, in accordance with World Health Assembly resolution WHAT41, 18, to provide for a more comprehensive exchange of information between governments. Drug substances as well as finished dosage forms were included within scheme and provision was made for the exchange of officially approved, product specific prescribing information on the safety and efficacy of finished products.

The Committee wishes to encourage national authorities to issue certificates in precise conformity with the format proposed by WHO in order to ensure that clear details are given about a product's place of manufacture or assembly and whether WHO's standards of good manufacturing practice have been applied. Countries that have not already done so are urged to extend the system of licensing to manufactures of pharmaceutical products destined exclusively for export. The licensing system should ensure that these manufactures are subject to inspection, that they comply with internationally recognized requirements for good manufacturing practices, and that every reasonable precaution is taken to ensure that the quality of their products meets pharmacopocial specifications.

Poor bioavailability is a particular problem for products of low solubility or narrow therapeutic index. It can result in adequate drug absorption and thus treatment failure just as readily as products deficient in active ingredients. The bioavailability of essential drugs should continue to receive consideration since it is a key factor in quality assurance.

The Committee appreciates that the development of the Model List of Essential Drugs has provided a natural focus for the third edition of The International pharmacopoeia thus enhancing its potential value to developing countries. Essential drugs are accorded priority and all quality specifications are supported by classical methods of testing and analysis. A plan for a small quality-control laboratory in which most of these tests can be performed has been available since 1984. Since quality assurance of essential drugs is so important, the Committee recommends to national governments the setting up of such laboratories and the adoption of the international pharmacopoeia by those currently lacking the means to confirm independently the quality of the supplies they procure. In this context, attention is also drawn to the WHO publication Basic tests for pharmaceutical substances (20), which enables the identity of drug substances to be verified and gross degradation to be excluded when laboratory facilities for full pharmacopial analyses are not available.

The Committee emphasizes the need to extend the coverage of The International pharmacopoeia to include not only essential drug substances, but also the dosage forms specified in the Model List of essential Drugs, together with additional information on bioavailability, stability and recommended packaging and storage conditions.

Fake/Spurious Drugs Case - Lucknow, U.P.

On the 15th April 1993 in Fatehpur and on 22nd April 1993 in Rae Bareilly, 16th April 1994 in Ferozabad, the drug control authorities found on drug testing of chloramphenicol capsules that there was no Chloramphenicol content in them, whatsoever, under the Drugs and Cosmetics Act 1940 the drug was declared spurious, The drug had been ironically sold to large number of Government hospitals in U.P.

These spurious drugs had been distributed by M/s Alok Trading Company, Badshahnagar Railway Station, Faizabad Road, Lucknow, which on investigation was found to be non existent.

The manufacturers according to the label were Mac in Tosh Pharmaceuticals, Azadnagar, Chennai. On investigation Director, FDA, Tamil Nadu the company was found to be non existent. Following a raid it was found that the drugs were being manufactured by Drug India Company in Lucknow itself.

Several life saving drugs were also found to be spurious. Spurious drugs were being manufactured using the brand names of some essential and life saving drugs e.g. Rifampicin an important anti TB drug, Cephalosporin an important antibiotics, Norflox, Salbutamol - anti asthmatic drug, etc.

On 21st January 1995 in Mahanagar thana, Kamal Engineer Arora, a drug inspector had filed a case against Alok Trading company for manufacture of spurious drugs and use of fake license.

Several cases are pending in the courts and many of the manufacturers have been granted stay orders or their files have been closed, and the investigation slowed down due to interference and pressure from higher ups.

With support from a P.P.S. level government official and State Drug Control lab personnel an attempt to protect the culprit has been made.

Dr. Aggarwal has been actively pursuing this case of spurious drugs, police has been pursuing the matter.

In the meantime a circular and a public advertisement no. 20F/4444/2934 dt. 18th March 1996 has been issued by Mr. K.C. Rastogi, State Drug Controller, from the office of the Director General of Health Services, U.P., making sales of Cosmetics, Food Supplements and Ayurvedic drugs from licensed chemist shops illegal. Their sales in chemist shop misguides the public into believing that these have medical value.

Yet the Cosmetics, Food Supplements and Ayurvedic drugs etc. continue to be sold and so do the spurious drugs. What happens to this case is being keenly watched by Consumer and Health Groups.

Issues that emerge

1. Need for strict monitoring of good manufacturing practice, G.M.P. strict standard adherence for those issued manufacturing licenses.

2. Strict monitoring of those issued drug sales license the name and photograph of the person should hang conspicuously in the chemist shop. Consumers must insist on examining it.

3. Adequate number of drug inspectors and government drug testing labs for Biological as well as chemical contamination.

4. Setting up of Drug Courts to finish these cases at the earliest without

granting stay orders, or letting the cases drag on with stringent punishment.

5. Development of an effective System of warning and quick withdrawal of such products.

6. Quick stringent action against those selling spurious drugs.

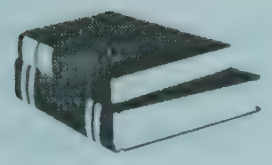
7. Public exposure and stringent action against those government officials involved in covering up such nefarious activities and providing.

8. Demanding of accountability of politicians putting pressure on government officials to protect culprits.

9. Alertness on part of the consumers to look at the manufacturers name, license number, expiry date, clarity of the label and collection of the products as well as the cash memo.

10. Reporting to the concerned authority if doubtful about a drug being fake and counterfiet with a copy to D.C.G.I.

17 The Lentin Commission Report



SOME IMPLICATIONS

J.J. DEATHS, THE LENTIN COMMISSION REPORT

"These pages describe and illustrate ugly facts of the human mind and human nature, projecting errors of judgement, misuse of ministerial power and authority, apathy towards human life, corruption nexus quid pro quo between unscrupulous, license holders, analytical laboratories, elements in Industries Department controlling the awarding of rate contracts, manufacturers, traders, merchants, suppliers, the FDA and persons holding ministerial rank.

None of this will be palatable in the affected quarters. But that cannot be helped".

Thus starts the introduction of the Commission of Inquiry into the J.J. deaths headed by the late Honourable Mr. Justice Bakhtawar Lentin.

The Lentin Commission report is not a report of 14 needless deaths, it is about the rot that has afflicted our health care system, because this noble profession is increasingly being controlled by men greedy for money and power.

The Story in Brief

Between 21st January and 7th February 1986, 14, patients died in J.J. Hospitals, they died of a cause totally unrelated to the treatments that brought them there. They died of toxicity or should we say poisoning by the adulterated glycerol given to them.

The toxic adulterant was Diethylene glycol which was present in the concentration of 18.5% as found later i.e. 3½ times the lethal dose, even 1% of Diethylene glycol is known to cause damage. These patients died of acute renal failure as rapid necrosis of the kidney tissue took place.

This adulterated glycerol meant for Industrial purpose was sold by the Kailash Co. to Alpana Pharma with the former knowing that it was to be used for Medicinal purpose. This was not a mistake, nor an act of carelessness. It was an extremely conscious act motivated by greed for more profits.

Alpana Pharma which provided the glycerol to J.J. Hospital did not have its own manufacturing unit or drug testing lab.

Its tender to supply glycerol had been accepted by the Tender Committee in gross violation of the rules of acceptance of tender.

Mr. Ramanlal Karwa of Artichem Lab. On behalf of Alpana Pharma had paid Rs. 18000 to Dr. R.D. Kulkarni the key

person in the Tender Selection Committee to conduct bioavailability studies, which were actually not expected to have been conducted. The real reason for payment being the clearance of the tender. This tender was the 5th lowest, with obviously no advantage such as better quality control assurance. Lentin Commission states that "Dr. R.D. Kulkarni awarded the rate contract to Alpana Pharma for extraneous consideration".

Licensing authority

The issuing of licenses was in the hands of men found to be corrupt. The Deputy Drug Commissioner of Maharashtra Mr. S.M. Dolas enjoyed great powers, even more than the Drug Commissioner. He managed to supersede his seniors and spend 20 years out of 28 years of his official career posted in Mumbai when transfers are ordered after every 3 years. Any attempt at posting him out was thwarted. He was protected by previous and present health ministers whom he obliged in return.

He had a departmental enquiry against him on charges of negligence, inefficiency, maladministration, dereliction of duty.

Drug Testing Laboratroy

Chem Med which gave the clearance to this ' industrial' glycerol of being of standard quality, did not conduct the required tests. Had it not been for Chem 'Med's certifying of glycerol to be of standard quality, it would not have been supplied to J.J. Hospital. The Commission noted that "Chem Med was found guilty several times of gross irregularities in matter of analysis of drugs and or issuance of Test Reports without actually carrying out the tests and had accepted and suffered the punishments in respect thereof". It is obvious that this had happened not for the first time, it was a pattern.

Tender Committee

The key person in the Tender Committee was Dr. R.D. Kulkarni, Prof. and Head of Pharmacology Department of J.J. Hospital, Dr. R.D. Kulkarni had not only accepted Rs. 18000/- from Alpana Pharma, but had accepted Rs. 1 lakh from Hoechst and Rs. 1.5 lakhs from Himalaya Drug House for his clinical research centre. The accounts of which he was free to operate, and "these accounts were not taxed, but were put to personal use in repair of car, in building of house, and dry cleaner bills."

The inaction of the Highest authorities in J.J.

Even while the patients started dying and the culprit drug was more or less identified, the toxic glycerol continued to be given in Opthalmology Department as anti-oedema agent. This continued usage and non-withdrawal of the drug continued for a few more days.

This was due to total inaction by the Dean, Dr. R.S. Chandrikapure and the

Medical **Superintendent** Dr. V.G. Deshmukh, even when they were informed. "The letter requesting urgent actions by the nephrology department sent through their ward boy was returned unsigned because the latter had not brought a pen to sign it with, and Dr. Deshmukh was going out shopping."

About these 2 luminaries Justice Lentin has the following to say "the captain and his Lieutenant failed in their duties and abdicated their responsibilities and abandoned the ship in the hours of crisis. These two were as negligent, inefficient, brutal, cynical and lazy in doing their duty, as their incalculable for shrugging off responsibility, showing neither thought nor remorse. They are unfit to hold any post involving responsibility."

The Pharmacology Department

The Clinical Pharmacologist Dr. S.V. Shaligram rather than immediately withdrawing the toxic drug in question was more interested in conducting animal studies to identify the toxic drug. To him Justice Lentin said during the proceedings "You seemed to have reached for the moon and ignored the sick men at your feet".

About Health Ministers

Justice Lentin states that "they have encouraged corruption, favouritism, deliberate violation of the Act and Rules by their own acts of omission and commission, intentionally and knowingly performed with a view to confer favours or ministerial largesse in the form of transfers and posting of choice, undeserved promotions of FDA officers and concessions, cancellations, of stringent orders or withdrawal or withholding of mandatory prosecution in accordance with the provision of the Act against the licenses viz. Manufacturers and repackers etc."

Since a very large percentage of the drugs registered in the country are registered in Maharashtra – the way the drug industry and the FDA functions in Maharashtra definitely effects others.

Probably many more have died, and many more will die slowly. They will remain undiagnosed and uncompensated, in the absence of any systematic monitoring of adverse drug reaction even to known hazardous drugs.

The tragedy continued thereafter in another form. FDA officials incharge of investigating the tragedy tried to shield the guilty and give false reports. "Even the contaminated bottles of adulterated glycerol were not seized by FDA." This was brought out by the Lentin Commission.

The Lentin Commission

The Lentin Commission was set up on orders from the Supreme Court to Maharashtra as a response to a letter to Justice Bhagwati by Dr. N.H. Antia, Director, Foundation for Research in Community Health, FRCH, about the

need to investigate unbiasedly the J.J. Tragedy.

The Lentin Commission started its work on June 21st 1986 till 9th November 1987 and over 17 months worked over 301 hours. It examined 120 witnesses, recorded 3732 pages of evidence. It sat through all court vacations working full days often on Saturday. The commission staff and the 5 stenographers worked day and night and in record breaking 3 weeks got the report ready by deadline of 30th Nov. 1987.

It was the 1st commission that sat through, took cognizance of those witnesses who failed to tell the truth in the witness box and slapped perjury notices against 4 persons including 2 former health ministers.
The commission continued its diligent functioning inspite of threat of stoppage of funds, and inspite of suppression of fact and files, "delving out details from recalcitrant and hostile witnesses".

The court proceedings and the report itself have looked deeply into the legal, medical, social, ethical issues – and the report makes rich reading not merely in terms of bringing to light little known horrifying facts brought out, but because of evidence of literary skills, wit and countless courage.

The Lentin Commission's Terms of Reference and main recommendations are available with us.

Some of the statements made by Justice Lentin will go into the list of famous quotable quotes.

During the proceeding Justice Lentin reacting in one situation stated that "asking FDA officers as to who signed is like asking a tiger why it eats sheep".

On Page 139 of his report the Lentin Commission states about the FDA "The entire structure of FDA, at one time a prestigious body famous in all Asia has been corroded by rampant and unabashed corruption, deleterious indiscipline, naked favouritism, crude nepotism and gross ministerial interference at every stage and a "Sense of non-accountability all around".

At one point utterly disgusted with the evasiveness of Mr. SM.M. Dolas, Justice Lentin said "with the mental gymnastics of this witness I am sure he will become a commissioner and when the court sniggered, the judge added it is not a joke, it is prophecy".

Times of India aptly described FDA as "Friends of Drug Adulterators" Justice Lentin called the FDA "Father Dolas Administration".

Lentin advised a particularly brazen FDA official "Learn to keep alive in your breast the celestial fire called conscience. George Washington said that, have you heard of him?"
When asked as to what was unique about the commission Justice Lentin

stated that never in his experience of 14 years in High Court bench and 7 years in the civil court had he come across any case where barring a few exceptions, witness after witness came determined to suppress the truth and piling the blame on subordinates.

The Lentin Commission Report cannot and should not be treated as the investigation report of 14 deaths in J.J. Hospital, **it is a report of the rot which has been allowed to set in high and low places and this rapidly deteriorating trend must be stopped before it is too late. Stopping this rot is health action.**

An analysis of how much the Drug Acts have been used to bring the guilty parties to book shows that the act has been rarely implemented and no real deterrent punishment given. The question today in assessment of the drug situation is not just knowing the production, export and import figures but of "who" is taking the decision, "why" and at "who's costs". Till that is understood and interventions made accordingly it is unlikely that things will change. Those involved in corruption where health and lives of people are concerned need to b e exposed and treated as criminals by society. Where drug controls and legislations fail moral and public pressure alone can shame them into repetition of such acts being prevented, along with stringent punishment of course, of the guilty as well as their protectors.

When most of the government official indicted by the Lentin Commission on the J.J. Hospital deaths scandal have been exonerated by the government, Mr. L.V. Raykar, Assistant Commissioner, FDA has had to bow out unceremoniously as he has been dismissed by the government. Mr. Raykar stated that the government acted very indictively against him because he assisted the Lentin Commission during its enquiry. Dr . R.S. Chandrikapure was reinstated as Dean of the government medical hospital, Nagpur and Dr. S.V. Shaligram as Professor of pharmacology at the Grant Medical College, Mumbai. Justice Lentin had estimated that Dr. Hiray had collected about Rs. 40 to 50 lakh in 1981. An independent enquiry by a retired judge, MD Kambli has confirmed the Lentin Commission findings on how the former Maharashtra Health Minister **Dr. Baliram Hiray** lied his way to ill-gotten wealth. Report recommended that Hiray should not be appointed to any public office, elective or otherwise.

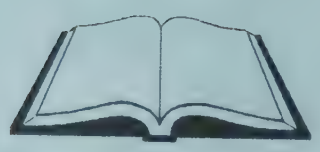
Lentin Commission recommended that drugs found to be substandard or spurious should be made public along with the names of the manufacturers and the batch numbers. This is being done.

Where indictment of the guilty is concerned the story has been similar to the dozens of cases filed against violators of Drug & Cosmetics Act, or where commissions have held those responsible of violations guilty.

What has been the track record of action taken against the guilty? The non-implementation of the judgements makes acts like Drugs & Cosmetics Act a farce for the people, while loopholes continue to be used against the people by the vested interest.

Monitoring the number of drug related cases in the courts, in the past &at present, the action taken or not being taken & the time lag between the two, must be given high priority. These must be reported in the parliament, as regularly, as the budget announcement.

Exploitation in the name of medicine must stop.



Ref.

1. *Lentin Commission Report, Govt. of Maharashtra.*
2. *J.J. Deaths the Lentin Commission Report, Dr. Mira Shiva, VHAI.*
3. *Indian Express Rupa Chinai's coverage of the Lentin Case.*
4. *TOI 25.11.92.*
5. *The Daily, Aug. 12, 1991.*

18 Strengthening Drug Regulation

Mashelkar Committee Report

Expert Committee on comprehensive examination of drug regulatory issues including the problem of spurious drugs.

Summary Highlights

The committee under the Chairmanship of Dr. R.A. Mashelkar, Director CSIR was set up by the Ministry of Health Family Welfare, GOI. It submitted its report on November 2003.

1. It took cognizance of the concern expressed by the Supreme Court by NHRC and Members of Parliamentarians about the need to improve the Drug regulatory system.

2. The Committee was asked to examine the regulatory structure, extent of the problem of spurious and substandard drugs, review the drugs and Cosmetics Act address the core issues and give recommendations and provide a road map.

3. The committee examined broader issues and looked at the recommendations made by earlier committees the extent of progress made, the bottlenecks faced in the implementations of the recommendations.

4. The Drugs and Cosmetics Act of 1940 while it has been amended during the 56 years, it has not been enforced satisfactorily in many states.

5. The interpretations of the provisions of the law and its implementation are not uniform nor was the level of competence of the personnel.

6. The committee noted that on the basis of assessment and recommendations of several committees Ministry of Health and Family Welfare proposal to expand and upgrade Central Drugs Standard Control Organization, several posts and testing labs were created. These posts could not be filled due to *'administrative complexities'* and the posts have lapsed.

7. In 1999 the Pharmaceutical Research & Development Committee (PRDC) had recommended comprehensive strengthening of Central Drugs Standard Control Organization. Unfortunately no infrastructure improvement in man power had occurred.

8. The idea of setting up of National Drug Authority was started with the *Hathi Committee* (1975) was

reiterated by Drug Policy (1986) and Drug Policy (1994). This had not been implemented.

9. The committee concluded that the problem in the regulatory system in the country were primarily due to inadequate or weak drug control infrastructure at state and central level, inadequate testing facilities shortage of drug. Inspectors non uniformity of enforcement, lack of specially trained cadres for specially regulatory areas, non-existence of data bank and non availability of accurate information.

10. The committee felt it was essential to strengthen the existing organization for it to undertake functions envisaged under National Drug Authority. A strong well-equipped and professionally managed CDSCO which could be given the status of Central Drug Administration was needed. Additional proposal to create such a structure and strengthen state level regulatory apparatus with complementary roles of centre and the states, while ensuring uniform and effective implementation has been considered and recommended by the committee.

11 The Committee noted that the onus of monitoring drug manufacturing standards drawing and testing of samples, taking legal action against infringes rested primarily with state drug regulatory agencies. It was essential for state government to strengthen state drug control organizations.

12. On the basis of the questionnaire sent and information collected from the 31 states/UTs only 17 drug testing laboratories were found to be functioning. Out of these only 7 were reasonably equipped/staffed, while others were poorly staffed without bare minimum equipment.

13. Since *Hathi Committees'* time, the states were repeatedly requested to set up intelligence cum legal cells, only 10 had so far been set up though the level of some of their functioning and effectively was not clear.

14. On the basis of information collected by the Committee the actual number of bulk drug manufacturing was 1333, licenses issued was 4534 for formulators 134 large volume parental, 56 vaccines. The total number of manufacturing units engaged in bulk drug and formulation production was 5877 and not 20,000 as often quoted according to the Committee. Besides this there were 199 medical device units 638 surgical dressing 272 disinfectant 4645 loan license 318 repackaging units, 1806 blood banks, 2228 cosmetics units and

2870 the units not covered under the above categories.

15. Committee examined reports, statistics and media reports about spurious drugs. The extent was from 0.5 based on cases analyzed by state regulatory authorities to 35% (ascribed) WHO.

WHO has responded to query, the validity of the WHO statement that about 35% of worlds spurious drugs are being reported from India that **there is no actual study by WHO that concludes that 35% of world's spurious drugs are produced in India.**

16. The Committee concluded that it is essential to evaluate systematically and scientifically the extent of the problem. A study was recommended and is being undertaken.

17. The Committee concluded that while there were various effective punitive measures against manufactures and distributors of spurious drugs in the present Drugs and Cosmetics Act, more deterrent measures were needed. Committee strongly felt that all offences related to spurious drugs should be made COGNIZABLE and NON BAILABLE. Apart from penalties of stiff fines and imprisonment for life, specially for those cases, which had resulted in grievous body harm or loss of life, death *penalty* was required to be provided.

18. Committee noted with dismay that offences related to spurious drugs remained undecided for years. Speedy deterrent punishment that was 'severe', 'sure' and swift was recommended.

19. For effective and successful implementation, involvement of police authorities besides drug inspectorate was recommended at an early stage, by authorizing them to file prosecution for spurious drugs under the Drugs and Cosmetics Act. Changes in statutory provisions including fresh legislation for both punitive and deterrent punishments for those involved in criminal acts of manufacturing and distribution of spurious drugs are needed according to the Committee.

20. Committee recommended that where spurious drugs causing grievous hurt on death was concerned punishment should be enhanced **from life sentence to death.** Penalties for other offences should be made more deterrent.

21. While prevailing penalties are decided by the courts following normal legal procedures. Committee recommended deterrent action against such offenders in the investigation level itself by making specific provisions in the Drugs and Cosmetics Act that will allow persons indulging in offences related to spurious drugs

to be detained for a minimum period.

22. Specific recommendations for amending Drugs and Cosmetics Act 1940 have been given.

23. Committee is of the view that the responsibility for effective management, of the issue of spurious drugs, their manufacture and distribution, lies not only with the drug regulatory agencies at the centre and the states, of the police, but also with all the other stake holders. i.e. medical with paramedical professionals, pharmaceutical companies, distributors and retail trade, patients, media, NGOs and public at large.

24. Many stakeholders such as regulatory agencies and pharmaceutical companies have sufficient expertise to detect and analyze spurious drugs.

Others need to be made aware of the problems involved the potential grievous harm which can be caused and the initiatives they could and should take in tackling this menace. Committee suggests that industry and trade associations should play active role.

25. The committee report is divided into two parts. (Part A and Part B)

Part A deals comprehensively with the issue of implementation of all the rules and regulations which guide monitor and control the activities of the providers of health care system.

It provides design of central drug administration its size, functions and sharing of the responsibilities vice versa the states, including directions for licensing of health food and dietary supplements, therapeutic foods, Indian system of medicine and herbal products, over the counter drugs, medicines and diagnostics.

Part B covers problems concerning spurious and substandard drug and measures to deal with it.

(Ref: Expert Committee Report on Comprehensive Examination of Drug Regulatory issues including problem of spurious drugs by Ministry of Health & Family Welfare, GOI, November 2003.)

19 Schedules of Drugs

A number of schedules are given in the *Drugs & Cosmetics Act 1940* and *Cosmetics Act 1945*, which are of theoretical and practical importance to the dispensing pharmacist.

Schedule G – List of substances that are required to be used only under medical supervision and which are required to be labelled accordingly. E.g. Insulin, anti-histiminic drugs, etc.

Schedule H – List of substances that could be dispensed only on the prescription of a registered medical practitioner. E.g. sulpha drugs, antibiotics, pentazocine, diazepam, chlordiazepoxide etc.

Narcotic Drugs – List of narcotic drugs e.g. pethidine, morphine, etc.

Schedule X – List of psychotropic substances e.g. phenobarbitone, its salts.

Schedule J – Disease and ailment, whatever name described, which a drug may not purport to cure.

Rule 106 Disease which a drug may not purport to prevent to cure:

1. No drug may purport or claim to prevent or cure or may convey to the intending user thereof any idea that it may prevent or cure, one or more of the diseases or ailments specified in schedule J.
2. No drug may purport or claim to procure or assist to procure or may convey to the intending user thereof any idea that it may procure or assist to procure, miscarriage in women.

Schedule N – List of minimum equipment and other facilities a pharmacy should possess.

Schedule P – Life period of drugs. Usually these are specified on the label. When it is not specified, it should be used only for a period of 5 years from the date of manufacture.

Schedule V – Standards for patent and proprietary medicines containing vitamins e.g. prophylactic, paediatric, therapeutic. While identifying such medicines containing vitamins, we should identify their use such as paediatric, prophylactic and therapeutic (identified on the lables).

Schedule W – List of drugs which can be marketed under generic names only e.g. aspirin and its salts, Chlorpromazine and salts, ferrous sulphate, piperazine and its salts.

At present narcotic drugs and psychotropic substances are controlled by the following Acts:

1. The Drugs and Cosmetics Act 1940, Drugs & Cosmetics Rules 1945.
2. The Narcotic Drugs and Psychotropic Substances Act 1985.

Prescription for Psychotropic Substances and Other Schedule Drugs

The following conditions are made statutory as per the Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945.

Sale of Schedule Drugs (Schedule H, Narcotics, Schedule X)

Schedule H, Narcotic and Schedule X drugs should not be dispensed except on the prescription of a registered medical practitioner. Prescriptions ordering such drugs should not be dispensed more than once unless otherwise specified.

If the prescription contains a direction that it may be dispensed more than once and at specified intervals, it may be repeated according to such direction only.

At the time of dispensing a prescription, the dispenser should note his/her name, address and the date of dispensing above the signature of the prescriber.

In dispensing Schedule H, Narcotic drugs and Schedule X prescriptions, no substitution should be made.

In case of narcotic drugs and phenobarbitone the following should be entered at the time of supply:

1. The prescriptions should be in duplicate.
2. One copy of the prescription should be retained for at least 2 years.
3. Separate bound and paged registers should be maintained for each drug and should contain:
   a. Date of supply, opening and closing stocks of drugs on each day and relevant bill numbers.
   b. Name of the drug, name of the manufacturer and batch number.
   c. Name and address of purchaser.
   d. Date of prescription and name and address of the registered medical practitioner.
   e. Signature of person under whose supervision supply is made.

The cash or credit bills should bear the signature of purchaser with his address. Transactions of Schedule X drugs should be recorded in separate registers in which; in addition to the above details, the quantities purchased should be recorded along with name and address of supplier and his licence number.

Storage of Schedule X Drugs & Narcotic Drugs

Drugs specified in Schedule X and Narcotic drugs should be locked in a separate drawer or cupboard reserved for their storage, in a part of the establishment which is separate from the remainder of the premises and to which the customers have no access.

Schedule Y specifies requirements and guidelines on clinical trials, imports, and manufacture of new drugs.

Ref.: Drugs and Cosmetic Act as quoted in CHAI-CMAI Joint Formulary 1994.

20 Drugs not to be Used by Pregnant and Breast feeding Mothers

Effect of Drugs During the Different Trimesters of Pregnancy

Some drugs affect the mother and some the foetus. Sometimes drugs are needed for some chronic condition, benefits and risks must be assessed before prescribing or consuming a drug in medicines.

The nine-month period of pregnancy is divided into three stages, each of three-month duration. These stages are called trimesters. A drug may exert different effects on the mother or the foetus or both depending in which trimester of pregnancy it is being used.

The first three months or the first trimester of pregnancy is the most critical period. Certain drugs may adversely affect the development of organs in the foetus. Very severe defects may result in miscarriage.

During the second trimester, drugs may retard the growth of the foetus, which can also cause low birth weight.

Drugs taken during the third and last trimester may cause breathing problem in the newborn baby or may cause premature/delayed birth.

Drug in Pregnancy

Some drugs are dangerous throughout pregnancy.The table below lists drugs that definitely should not be given during pregnancy and those which are best to avoid if possible.

Drugs to be avoided or used with caution during pregnancy.

Drugs	*Avoid*	*Caution*	*Comments*
Antibiotics			
Chloramphenicol		3	Avoid using long courses. Causes 'grey' baby syndrome.
Co-trimoxazole		3	Can cause abnormalities and blood disorder in the baby.
Gentamicin		1,2,3	Only use if really necessary
Griseofulvin		1,2,3	Use topical drugs if really necessary
Metronidazole	1	2,3	Use lower doses (see following page for more details)
Nitrofurantoin		3	May affect the baby's blood if used near to delivery
Streptomycin		1,2,3	Can damage hearing of the baby. Note: treatment for TB should not be interrupted or postponed during pregnancy.Refer to your National TB guidelines for drugs of choice in pregnancy. If isoniazid is use, pyridoxine

			should also be given to prevent peripheral neuropathy.
Teracyclines	1,2,3		This includes doxycycline.
Anti malarials			
Halofantrine (Halfan)	1,2,3		
Mefloquine (Lariam)	1	2,3	Only use if no other drug is available.
Pyrimethamine/ Sulfadoxine (Fanisdar)		1,2,3	If possible use quinine instead
Quinine			The benefit outweighs the risk. Preventive measures are very important such as sleeping under a
net			and taking prophylaxis, e.g. chloroquine each week.
Antihelmintics			
Albendazole		1,2,3	Known to cause abnormalities in animal studies.
Mebendazole	1	2,3	Consider using piperazinne if appropriate.
Praziquantel		1,2,3	If possible wait until after delivery.
Thiabendazole		1,2,3	Although thiabendazole is no longer on the WHO essential drug list, it may still be widely used.
Analgesics			
Aspirin & other NSAID	3	1,2	Use paracetamol
Antiepileptics			
Carbamazepine		1,2,3	Benefit outweighs the risk
Pheobarbitone		1,2,3	If possible use only one
Phenuytoin		1,2,3	Use drug and monitor blood levels
Miscellaneous			
All cancer drugs	1,2,3		Seek specialist help
Aminophylline/ Deophylline		3	May cause irritability in the baby if used near delivery
e.g. diazepam		1,2,3	Avoid regular and prolonged use.
Vitamin A (Retinol)		1	Large doses may cause abnormalities in the first trimester.

1= first trimester (1-3 months)
2=second trimester (4-6 months)
3=third trimester (7-9 months)

Avoid = do not use at all
CAUTION = only use if the benefit outweighs the risk.

If the drug is not listed above it does not mean it is safe to use in pregnancy. Please check other literature for more information.

Source: Practical Pharmacy, April – June 1988, Issue 9. (*Towards Comprehensive women's health programmes and policy).*

Lactation

Most drugs can pass from the mother's blood stream into the mother's milk just as they pass from the mother's bloodstream into the baby's bloodstream. A baby who is being breast-fed will thus receive small amounts of the drugs that the mother is receiving.

There are certain drugs which do not pass into the mother's milk at all because of their chemical nature and there are some which do pass into the breast milk but in amounts too small to produce any harmful effects on the baby. However, there are certain drugs for reduced milk production in the mother that produce unwanted effects on the breast-fed baby. It is always advisable for the mother to consult the doctor before taking any drug while breast-feeding the baby. As far as possible, we must try to avoid drugs rather than breast-feeding. When the mother is suffering from chronic conditions, and has to regularly take drugs, and the doctor should decide whether she should continue breast–feeding. In case she is allowed to continue breast feeding the baby should be closely monitored (observed) by the doctor for any possible harmful effects. It is important to remember that apart from a few chronic conditions a mother is never advised to refrain from breast-feeding.

Advice on breast-feeding varies with the drugs prescribed.This is discussed in this column wherever necessary.

Drugs to be avoided or used with caution during breast feeding

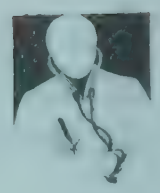
Drugs	*Avoid*	*Caution*	*Comments*
Chloramphenicol		X	Only use if no other antibiotic is suitable
Ciprofloxacine	X		
Co-trimoxazole		X	Especially if the baby has jaundice.
Metronidazole		X	Avoid large single doses e.g. 2g daily
Tetracyclines	X		This includes doxycycline
Others			
Aspirin	X		Use Paracetamol instead
Benzodiazepines e.g.diazepam		X	Avoid repeated doses. May cause weight loss and tiredness in the baby.
Carbimazole	X		May effect the baby's thyroid function
Cimetidine		X	A significant amount is found in breast milk – not known to be harmful but advisable to avoid using.
Ephedrine		X	May cause irritability and disturbed sleep patterns in the baby.
Iodine (includes cough mixtures with iodine)	X		It appears that iodine is concentrated in breast milk and can severely affect the thyroid gland of the baby. If absolutely necessary to treat the mother then advise to stop breast-feeding.
Oestrogens (in oral contraceptives)	X		Reduces the milk supply, Choose an oral contraceptive that contain progesterone only.

Phenobarbitone		X	May cause drowsiness and inhibit the baby's suckling reflex.
Thiazide diuretics e.g.bendrofluazide		X	Large doses may reduce milk supply

If a drug is not listed in the table it does not mean that it is definitely safe to use. Please check other literature for more details.

Source: Practical Pharmacy, April – June 1998, issue 9 as quoted in Chapter on Women & Medicines in Toward Comprehensive Women's Health Programmes and Policy.
Dr. S. Srinivasan & Dr. Mira Shiva, Sahaj, WAHI, 2002

21 Drugs Misused for Unethical Clinical Trials



It was the women's organizations that first raised the issue of unethical clinical trials.

NET EN

The drug involved was injectable hormonal, contraceptive *net-en* i.e. *norethisterone enanthate*. The objections raised were due to:

- absence of informed consent
- denial of unbiased information
- the potential health risk, due to known adverse drug reactions
- absence of accountability and liability in case of problems
- non availability of basic health services which are essential to exclude women for whom Net En would be contraindicated e.g. diabetes, hypertension hepatitis etc.

The PIL was filed by *stree sanghathana*, Hyderabad, *Saheli*, Delhi, *Chingari*, Ahmedabad and AP Civil liberties Committee.

Many of these concerns were also expressed when Depo Provera injectable hormonal contraceptive was introduced in India by Up John through Max Pharma – no introductory trials were conducted. It was women health activists who exposed the double standards in the package insert provided with the drug in India, and the one given in US.
Here the list of contraindications was small, unlike the one provided in US.

Based on recommendations of the Drug Consultative Committee and the Drug Technical Advisory Board. Depo Provera was not included as part of the contraceptives offered under the National Family Planning Programme. It was to be sold under prescription as a schedule H drug in the private sector.

The need to promote rational drug use in reproductive health comes up again as a critical issue. The need for unbiased drug information excluding those for whom it is contraindicated, ensuring continuity, and follow up, dealing with side effects is evident.

NORPLANT

Norplant is a levonorgestral based contraceptive.

Norplant constituted of 6-match stick like rods implanted subdermally under the skin in the arm, inserted following an incision given after using local anesthesia. The silicone coated capsules/ rods each contain 36mg of the hormone levonorgestreal.

The hormone is slowly released from the body over 5 years, in dosage lower than oral contraceptive.

Norplant 2 consisted of 2 rods of the same hormone. It was produced by Leiras of Finland, distributed through Population Council, with loans from

World Bank & USAID in several countries. Majority of the users being in developing countries, most being in Indonesia.

Norplant being 'progestin only' according to its researchers has lesser side effect, besides its efficacy, reversibility and invisibility of the method.

Norplant works by:
Suppression of ovulation, reducing number of eggs

Thickening of cervical mucosa, making it difficult for the sperms to move to fertilize the egg.

May be hormonal suppression of the endometrium – i.e. inner lining of the uterus.

Contraindications include cardiovascular disorders, abnormal vaginal bleeding, benign or malignant tumours known or suspected breast tumours to be avoided in pregnancy and till 6 weeks after childbirth in lactating mothers after delivery. According to Population Council Manual 1990, WHO warns about the need for regular medical checkups and follow ups in women using norplant, who are anaemic, have hypertension or diabetes.

A study on 234 norplant users found 66% had irregular cycles in the 1st year. In fifth year it decreased to 35%. World trials have shown 60-100% norplant users expressed irregular bleeding being most severe in the 1st 6 months. 20-30% pregnancies in norplant were ectopic (Shoupe 1991).

Most frequent side effects are menstrual bleeding. Disruption of menstrual cycle in 60% norplant users and 10% develop ovarian cysts. Others are severe headache, nausea, dizziness, weight gain or loss, nervousness and depression, scarring, acne and other skin disorders and infections at the implantation site. These are considered minor side effects. (Gupta 2000).

The users are healthy women 'not sick' patients usually with double & triple burden of work on their shoulder. Using this for contraception, having to live and work day in and out, feeling depressed with headache and nausea, with menstrual chaos, with all its religious and cultural taboos and practices is more than 'minor side effect'.

There is an increased risk of ectopic pregnancy, if pregnancy does occur and a risk of heart and other birth defects in the unborn child (Nair 1989, p. 29-30).

Norplant is known to affect thyroid and adrenal glands, blood sugar levels and blood coagulation factors. Impaired vision and partial loss of use of the arm has been reported from several countries.

Long term effect on breast fed infants, whose mothers have had a norplant inserted soon after delivery is not known.

There is undoubtedly some continued health impact of the implant even after

5 years when it should be removed. WHO guidelines require its removal after 5 years. Unfortunately 30% women in Indonesia with norplant were lost to follow up. Many were lost to follow up in Brazil, Bangladesh etc. Some migrates for work, others being displaced.

The effect on progeny, if pregnancy occurs, while some hormonal effect is still present, eventhough the contraceptive effect may be gone, is a matter of concern to women's health group.

Health provider's refusal to remove it is the other problem. Because of the cost involved, there has been unwillingness to remove the norplant. More over skill training for removal of norplant, when fibrosis, scar tissue has already formed at the incision site, making removal a little more difficult.

In India 2 rod trials had been done reaching up to phase 3. Norplant pre introduction studies were held in 1984 but were abandoned within 2 years because the manufacturer stopped making the elastomer used in the 2 rod model. The elastomer was feared to be carcinogenic. Many legal cases by women on whom this had been used for breast reconstruction and who developed problem were filed in US courts.

Under the auspices of ICMR fresh trials of norplant (R) the 6 rod in 10 medical colleges were started in 1993, funded by USAID and IPPF.

In 1993 several women's groups and health groups called for a stoppage of introduction of Norplant R in National Family Planning Programme. Since Norplant 2 and Norplant R were using 2 totally different drug delivery systems, trial results of the former could not be automatically extrapolated to Norplant R. New Phase III trials were designed where Norplant R was offered as a contraceptive choice from amongst others in a cafeteria approach to select volunteers.

The concern expressed by those involved in women's health advocacy was the need to improve the basic health services, and reproductive health services to women. Without their back up for follow up services, more costly, provider controlled, technological fixes, targetted at women, as part of the demographically driven agendas was not in the interest of women. Increasing 'choices' could not be limited to 'contraceptive choices' alone. Contraceptive choices could not be really made – without exclusion of those conditions, presence of which were contraindicated. Basic facilities for taking blood pressure, testing for sugar to exclude diabetes. M P blood test for malarial parasite, sputum AFB for TB – were still wanting in large parts of the country.

Results showed 57.9% of the 1466 women in research trials discontinued their use before 5 years.

28.5% did so because of menstrual

problems. Other side effects reported are deep vein thrombosis, arthritis, dimness of vision, infective hepatitis.

In 28 cases difficulty was experienced with removal.
Forum for Women and Health, Mumbai, in recording first person accounts of norplant users in Baroda, found that none of the women on norplant were aware that they were participating in a clinical trial. They were not checked for diseases, the presence of which is a contraindication for norplant use. The Forum for Women's Health found that poor women, jobless, with no permanent address were enrolled in the trials, and therefore it was not a surprise that many were lost, and became untraceable during trials in Thane. Many women in Delhi trials when contacted by MFC, Jagori, Action India complained that they had not been told about the possible side effects and when they wanted removal, doctors refused to remove the norplant.

Inspite of tremendous international pressure from Population Control lobby the human clinical trials of *norplant* in India were resisted by groups and organizations involved in women's health and reproductive health advocacy till basic health services, reproductive health services were improved.

Concerns were:

- again targeting of women with a long acting contraception (5 years)
- with unlikeness of its removal, in presence of problems like bleeding
- costly and imported contraceptive technology
- requiring special training of health personnel for insertion and removal, as minor surgical procedure was involved.
- absence of follow up support services, when basic health availability of reproductive health services themselves were in bad shape.

The issue of following certain ethical norms was raised again and again, specially in relation to double standards in contraceptive reproductive technologies targeted at women e.g. antifertility vaccine, norplant and quinacrine. The Helsinki charter on human clinical trials was repeatedly quoted.

QUINACRINE

The unethical quinacrine trials

Quinacrine an anti malarial was unethically and illegally used as a contraceptive on several thousand women in India.

7 pellets (of dosage between 216 to 324 mg) of quinacrine were inserted intravaginally, in the uterus near the fallopian tubes. The pellets on dissolution would cause corrosive action on the wall of the uterus, but also near the opening of the fallopian tube,

causing scarring and adhesions and thereby occlusion. This being called 'medical sterilization' rather than 'surgical sterilization'. What was not told to the women, was that there were some minor as well as some major side effects possible, and that few women had developed peritonitis with the corrosive contents coming out of the fimbrial end of the fallopian tubes. Even ectopic pregnancy had occurred, where pregnancy followed, in cases where complete adhesions and occlusion of the tubes did not take place, ruptured ectopic pregnancy had occurred causing even death.

The human clinical trials were conducted in India without the knowledge of the drug controller of India, with out the clearance of ICMR, with WHO having categorically denied approval of the use of quinacrine as contraceptives. The trials were conducted by private practitioners and even an NGO.

Some of the practitioners were using quinacrine for sterilization, of illiterate poor women in Kolkata slums in Bengal, where it was called 'injection', even charging the patients for the 'injection'.

These clinical trials were financially supported by Dr. Kessel and Dr. Mumford, who also are the world's sole distributors of the drug. The drugs being manufactured by Sipharma of Switzerland. Kessel of International Federation of Family Health, Mumford of CRPS both US based, are known to have strong anti immigrant' position on immigration of people from the southern countries, into US besides subscribing to strong population control ideology.

It was because of the PIL (Public Interest Litigation) filed by Department of Community Health and Social Medicine(CHSM) of Jawaharlal Nehru University, by All India Democratic Women's Association(AIDWA) in the Supreme Court in 1998, that these concerns about unethical and illegal nature of the clinical trials of this hazardous product were highlighted. The Supreme Court ordered the cessation of the clinical trials. Way back in June 1994, WHO special programme of research development and research training in human reproduction WHO/HRD had categorically issued a **global warning against the use of quinacrine as a contraceptives and had urged researchers to undertake, and complete laboratory and animal studies for toxicity and carcinogenicity**.

Dalkon Shield

Dalkon Shield is a contraceptive IUCD and intra uterine contraceptive device, like Lippe's Loops, Copper T etc. Dalkon Shield, made of plastic, oval in shape with fins and a tail string to facilitate proper placement and removal. The tail made up of several filaments enclosed in a sheath, unfortunately acted like a wick, giving easy access to bacteria to move from the vagina into the uterus, causing PID (Pelvic Inflammatory Disease), (A.H. Robins) the Dalkon Shield case

highlights the need for post marketing surveillance, as many problems surface with time when the benefit risk ratio needs to be reassessed. Dalkon Shield is an IUD promoted by AH Robins, 2.8 million of which were marketed in US in the 1970s i.e. between 1971-74. Following reports of several thousand cases of Pelvic Inflammatory Disease (PID) at least 18 recorded deaths, several law suits, it was withdrawn in June 1974 from US markets and from outside USA in March 1975. About 1.4 million Dalkon Shields were inserted in women outside US, many as part of Family Planning Programmes, with 700,000 Dalkon Shields provided by US AID agencies many in India.

A.H. Robins held press conferences to reach the 4 million users to submit their claims by 30th April 1986. 192,000 claims were filed mainly from US. Many American women sought compensation out of the $2300 million. A Trust was set up to settle claims. Most Indian women out of the thousands inserted with Dalkon Shield failed to get any compensation.

Firstly because they were not even aware that it was Dalkon Shield that was inserted.

Secondly, with the insertion taking place in the family planning camps, there were no records left with them, nor with the providers, since the question of compensation came up much later and anyway camp records are inadequately kept.

Thirdly, the women were not even aware that compensation was available, for those who developed PID, ectopic pregnancy, infertility with all its psychological, physical and social consequences as a consequence of Dalkon Shield.

Fourthly, even if they had known, to seek compensation by poor illiterate women would not be easy. The over 2 decade struggle of Bhopal gas victims for compensation in the recognized biggest industrial disaster case in the world – where 4000 lives were lost immediately after the disaster on 2nd December, 1984, with about 6000 lives lost over the years and many thousands affected health wise – Bhopal is just one example – about justice delayed and justice denied. The scales are pitted against the poor, the victims. If the victims happen to be poor women, the discrimination is double. If the problem drug or technology is a contraceptive – one of the magic bullets for effective population control, then the women face triple discrimination, as women are seen as the 'population exploders' and the main cause of the population increase. The patriarchal mindset results in deflecting the attention from the 'inflicters of pregnancy'. Women rarely receive the understanding and the care they deserve, and not just in terms of safe, quality contraceptives but also in terms of the follow up required. The learnings from Dalkon Shield are crucial for future. Many contraceptives are actually pharmaceuticals or contraceptive technologies and the principles of

Rational Drug Use and principles of ethical clinical trials are also applicable to them. Also highlighted is the need for greater gender sensitivity and gender responsibility.

Hormonal Replacement Therapy (H.R.J)

H.R.T. has been used to deal with the post menopausal problems of women e.g. hot flushes osteo porosis etc. frankly being recommended for post menopausal women with problems, it is now being overused routinely, by many doctors for post menopausal women. Studies have shown a higher risk of breast cancer in women using HRT, the risk increasing by 2-3% each year. Studies conducted on use of HRT have been giving very varied and sometimes contradictory results

Antifertility Vaccine (AFV)

Since the anti-fertility vaccine trials have been a reality, the fear against injections for sterilization have emerged in many quarters. Resistance against polio drops by certain communities is a reflection of such fear.

Most vaccines are against a disease organism. The antifertility vaccine being developed, is not against the external 'sperm' but against the body's own hormone. Anti fertility vaccines are developed against oneself i.e. own human chorionic gonadatrophin (hcg) that provokes an auto immune reaction, hcg acts as an antigen, causing body to release antibodies against it.

The fear expressed is that unlike chemical action, with a certain known duration and severity of action, the immonological reactions are different and are unpredictable. More over it is known that immunological reaction is not limited to the targeted hormone i.e. - human chorionic gonadotrophin alone in this case, but also against other hormones, which may have, even partially the same structure i.e. LH (Lutienizing Hormone) and FSH (Follicular Stimulating Hormone), which are required for a balanced menstrual and ovulation cycle and thyroid functioning and could cause damage to pituitary and thyroid gland.

The AFV acts by producing antibodies against hcg, which is produced by the blastocyst i.e. early embryo. This leads to failure of this early fertilized ovum from being implanted in the uterus, and in its being actually expelled with the menstrual periods. (Richter 1990).

Women's Global Network for Reproductive Rights had given a call for a stoppage on research on antifertility vaccine and immunological contraceptives.

Letrozole

Letrozole is an **anti cancer** drug, belonging to schedule 'G' which is legally permitted to the prescribed only by oncologists i.e. cancer specialists. Used on 435 women for human clinical trial for **infertility**. These trials were conducted in private clinics without clearance from ICMR or DCGI. Death of the 'persons' involved in clinical trials in research jargon called "trial subjects" have taken place.

Anti cancer drug Letrozole is an expensive anti cancer drug. The drug is being promoted for "improving" fertility in infertile couples. This is being done by gynecologists, when no such indications is given by the original manufacturers 'Novartis' themselves. The drug regulators as well as the original discoverers of the anti cancer drug acknowledge its "embryo toxic" and "fetotoxic" potential. The drug is therefore recommended only for women with **breast cancer, who are post menopausal**.

In animal studies dosages of 0.003 mg/kg i.e., about 1/100th of normal human per kg dose have shown embryotoxic fetotoxic effects, increased post implantation loss, absence and shortening of renal papillae, dilatation of ureter, oedemia and incomplete ossification of frontal skull and metatarsals (bones of the foot). Letrozole in dosages of 0.03/kg (about 1/10th the normal human per kg dose) shows teratogenic effects i.e. causing foetal domed head and cervical vertebral fusion.

Some of Letrozole's side effects are ovarian tumours, liver cancer, hyper plasia of ovaries, sexual inactivity, abrophy of the reproductive tract. Other adverse reactions include hot flushes (19% cases), hypertension (8% cases), bone pain (22% cases), backpain (18% cases), joint pain (16%), limb pain (10%), breathlessness (18%) and cough (13%). The drug can also cause thrombosis, life threatening pulmonary embolism, myocardial infarction, angina, stroke and hemiparesis.

Letrozole is 1000 times more costly, than clomiphene which is the internationally accepted standard therapy to induce and augment ovulation in infertility.

Letrozole is schedule G drug and it can be sold only on prescription of a cancer specialist. Use of the drug, even if it is supposedly for research is illegal and unethical.

Source: Dr Gulhati, Editor, MIMS Editorial, September 2003.

ERYTHROMYCIN

ERYTHROMYCIN usually used as an anti infective, was tested on women as a **contraceptive**. Erythromycin was injected in the wombs of 790 women to test the drug for contraception. A paper was published in the journal contraception Jan. 2004 about these trials, conducted between August 1999 and October 2002. Here again the usage of the drug was for an indication different from the indication for which the drug was approved by the licensing authority.

Dr. Wishvas Rane, Using the poor as guinea pigs, Health Action, May 2004.

RECOMBINANT STREPTOKINASE was administered to trial subjects in Hyderabad to test its efficacy. Eight people 'trial subjects' died.[1]

CITALOPRAM an anti psychotic drug trials in Gujarat resulted in death of Dharmesh Vasava a 22 year old 'healthy' volunteer.[2]

1. Dr. C.M. Gulhati, Editor, MIMS India, September 2003.

Anti cancer drugs
2 chemical entities M_4N and G_4N were tested on 26 oral cancer patients in Regional Cancer Centre, Trivandrum, without clearance from ICMR and Drug Control authorities.[3]

Laws Related to Research and Ethical Guidelines

India is emerging as an important destination for human clinical trials. The clinical trials market on human subjects is expected to grow from $ 70 million to $ 300-500 million. A large number of trial subject volunteers are driven by poverty for the remuneration they may receive. Participation in clinical trials as central subjects has the same motivation just as it has been for selling of blood and body organs. Their use as guinea pigs in human clinical trials in violation of all laws of the land is a matter of concern requiring urgent intervention. The need for urgency in enactment of National Ethical Guidelines for biomedical research is obvious.

Any new use of an old drug which has been approved for a different indication or disorder, legally requires the drug to be treated as a "new drug" for the new indication, for which fresh government approval is required, under Rule 122-E of the Drug and Cosmetics Act rules. It requires toxicological studies, as well as both animal and human trials after getting approval from the Drug Controller General of India and in keeping with the National Ethical Guidelines for biomedical research on human subjects.

A **new drug** according to Drugs and Cosmetics Act section 122 (E) is defined as a drug already approved by the licensing authority, which is now proposed to be marketed with modified new claims, namely indications, dosage, dosage form (including sustained release dosage form), and route of administration.

According to Schedule Y some of the rules directly apply to doctors, such as conduct of clinical trials, and supply of medicines by dispensing doctors to their patients.

In 1988 schedule Y drugs i.e. Guidelines for new drugs imported or manufactured was included in the Drugs and Cosmetics Act of 1940, as an amendment. Recent pressure from private medical prescribers for inclusion of "off label drugs" i.e. for conditions, indications, other than for which, they are registered has been tremendous. The pharmaceutical industry and IMA have been lobbying hard for such a change (Mathew, Pharmabiz, 2004). In absence of adequate regulations, accountability, liability, drug reaction monitoring, with holding of unbiased drug information, the legalization of prescription of off label drugs is not in the interest of the consumer.

The ethical guidelines for biomedical research developed by ICMR are still merely ethical guidelines and the enactment is awaited.

The human subjects involved in the clinical trials are usually the poor

illiterate, unaware of their rights. Human Clinical Research in India is seen as a big market, due to more relaxed regulation, due to availability of larger number of such patients trial subjects in different age groups, suffering from different diseases who are willing to become trial subjects for small financial gains because of poverty. Those inducting them for clinical trials are basically pharmaceutical companies, private agencies or private practitioners. No permission is often sought from ICMR or DCGI, no protocols are reviewed, nor the national ethical guidelines for bio medical research on human subject are followed. In fact many are not even aware of them, and many so called 'trial subjects' are not aware that they are part of human clinical trials.

3 underlying principles of ethics for all research

1. Autonomy
2. Beneficence/non-maleficence
3. Justice

ICMR Ethical Guidelines for Biomedical Research on Human Subjects
Essential Components of Ethical Research

1. Essentiality, Voluntariness and Informed Consent
2. Community Agreement
3. Non-exploitation
4. Privacy and Confidentiality

(Ref: ICMR National Ethical Guidelines for bio medical research 2000.)

5. Precautions and risk minimization
6. Professional Competence
7. Accountability and Transparency
8. Maximization of the Public Interest and Distributive Justice
9. Institutional Arrangements
10. Public Domain
11. Totality of Responsibility
12. Compliance

The ethics of clinical research does not end with the signing of a consent document but encompasses the implementation, analysis and dissemination of research.

Informed consent means:

- Ascertaining that the individual know that they are being involved in a trial
- They have control as to whether or not they will participate in a trial
- They are informed about methods to be used
- The benefits and risks of participating in a trial
- Alternative forms of therapy

Understood Consent

The term and concept of UNDERSTOOD CONSENT is more important as it requires greater effort on part of the investigators to decide as to what is really important for participant to know, how effectively to communicate it, and how to ensure and measure their comprehension of this information.

Scientifically unsound research on human subjects is ipso facto unethical in that it may expose subjects to risks

or inconvenience to no purpose.
(Ref.: Council for International Organizations of Medical Sciences (CIOMS) International Guidelines for Biomedical Research involving human subjects, Geneva, WHO, 1995.)

"Issues such as use of placebos, standards of care and obligations to the participants and the community following the conclusion of the study have been intensely debated, in efforts to update 'Declaration of Helsinki and CIOMS Guidelines".
(Ref.: Richard Cash Ethical Principles and Health Research.)

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22 Life Style Drugs

Substance abuse and drug addiction to heroin, opium, cocaine, cannabis is well known and sales of these are addressed by the narcotic branch. There are many medicines which while required in medical therapy for certain clear indications are being increasingly misused and this an emerging public health problem that needs to be addressed.

These include many medicines from cough syrups like corex, phensedyl to sedatives and tranquilizers like diazepam (calmpose) and anti depressants like amphetamines etc.

Many young people have become dependent and deeply addicted to them, and need to consume them daily, purchasing them illegally and therefore at exploitatively high cost.

Sedatives Hypnotics

Morphine, pethidine, codeine, pentazocine, propoxyphene, buprenorphine which have legitimate use in extreme pain are often misused. These drugs are schedule X drugs requiring sales on prescription, as well as record keeping, but like many other drugs are being bought by addicts, which may include even some health personnel, who because of their access to such drugs, are also known to be develop dependence to these drugs.

Other drugs are being used in parties and to spike drinks of unsuspecting girls, who on being drugged are sexually exploited and black mailed. To hide their sense of shame many girls do not complain, emboldening the exploiters, who find easy targets in the growing pub and party culture.

Amphetamines

Amphetamines have been used by students to keep awake to study for exams. **Yaba** i.e. **meth amphetamine** was developed in Nazi Germany under Hitler's instructions to keep his soldiers awake for 2-3 days at a stretch without sleep.

Ice is crystal **meth amphetamine** synthetic stimulant that induces a feeling of high energy, heightened sexual desire, and wakefulness.

Modafinil is meant for treating narcolepsy i.e. excessive day time sleepiness and sold as mod alert by Sun Pharma in India. It is meant for sleep disorders and to be prescribed only by psychiatrists and neurologists.

Many young persons working in call centres are resorting to these drugs to beat sleep, because of their altered sleep cycle, as they work all night to be in with working hours in US. Disturbing their biological body clock, causing many health problems. The relationship of body's bio rhythm with health is known, but is constantly abused.

Other drugs being misused are Ecstacy, methyl phenydale.

The life style drugs affect the nervous system, by interfering with the chemicals in the brain. These drugs can cause chemical imbalance and **irreversible brain damage**, resulting in loss of concentration, memory and sexual performance.

Potency Drugs

Sildenafil citrate is the generic name of the potency drugs like viagra, penagra etc. which have a definite role in treating erectile dysfunction in men. Unfortunately their misuse as potency drug is rampant.

Due to unfounded fears about potency, arising out of guilt from masturbation, illicit relationship, visit to commercial sex workers, decreasing libido due to systematic diseases e.g. diabetes, insecurity due to increasing age and also a false belief in drugs effect in improving sexual performance, the potency drug market is large and growing.

Same as the viagra like potencydrugs sold in India are:

Sildenafil Citrate

Brand	***Manufacturer***
1-2-3	Aglowmed
Alsigra	Alembic
Androz	Torrent
Caverta	Ranbaxy
Edegra	Sun
Enthusia 100	Lupin
Enthusia 50	Lupin
Erix	Unichem
Manforce	Mankind
Niagra	Pure Health
Penegra	Zydus
Progra	Cipla
Rezum	Dr Reddy's
Uplift	Wallace
Vigreks	Medley
Wingora	Meyer

Large number of Ayurvedic drugs to increase potency abound. With the existing sexual crime rate and its worsening trend, the high percentage of "inflicted" pregnancies, called unwanted pregnancies, misuse of these drugs is a cause of concern to those involved in reproductive health, women's health and public health issues. The gender dimension in medicines used in reproductive health matters needs to be noted. On one hand we see more and more potency drugs, for men their misuse and overuse, when they are really not indicated. When it is simple guidance, counselling, psychotherapy that is really needed. On the other hand we see more and more contraceptives for women, some of them with potential health hazards. These are being prescribed for women for whom they should never be used and for whom they are contraindicated.

Cough Syrups

The misuse of cough syrup because they contain codeine and antihistamines is an increasing concern.

Some of the common drugs are:

Phensedyl by Nicholas Piramal	contains Chlorpheneramine and Codeine Phosphate
Corex by Pfizer	contains Chlorpheneramine maleate and codeine phosphate

Corex DX by Pfizer

contains
Chlorpheneramine maleate
Dextromethophan HB and Menthol

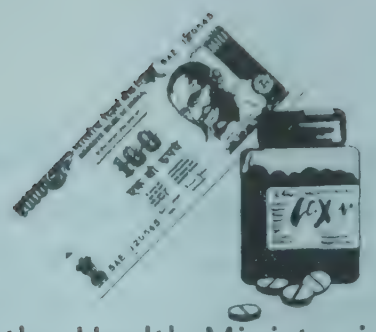
Cough syrups containing cough suppressants have an important role in conditions where coughing is painful, as in pleurisy etc. Codeine is an effective cough suppressant. It is also known to have a potential for misuse, and is being increasingly misused. Its use in a cough syrup is considered as safer than use of hard narcotic drugs like cocaine, brown sugar etc. by those addicted to cough syrups

As young people have greater access to money, decreasing family bondage, declining respect for teachers and elders, with "its my life""its my choice" attitude and approach to life, with drinking, pub and party culture becoming fashionable, increasing competition for college admissions, for jobs, increasing insecurity in life, the consumption of these life style drugs is bound to increase as the demand increases so will the supply and their consumption. Restrictions to curtail misuse is needed will be asked for, and it will be the patients who really need these drugs for medical therapeutic reasons, who will unfortunately face the difficulties in gaining access.

There is a need to address this issue with understanding and sensitivity. While for some people these drugs act as 'emotional crutches' in a superficial, callous and uncaring world, for others these drugs are reflection of their self destructive behaviour, where rebellion and frustration results in violence in the mind and action and is either perpetuated against self or against society. Substance abuse whether they are narcotic drugs or medicines with several health consequences both need to be addressed so also the causes.

It is a pity that while on one hand even essential facilities for diagnosis and treatment and essential drugs for people with health and mental health problems are not available, on the other hand a large section of our youth are knowingly or unknowingly destroying themselves with drugs having potential of irreversible brain damage, and ruining of lives. The issue is of course a matter of irrational use of medicines and is a public health concern, but more than that, it is a reflection of a creation of an increasingly selfish and uncaring society. This social pathology also needs to be addressed.

23 Drug Pricing



The Issue of Affordability

The Drug Control Authority under the Health and Family Welfare Ministry at the Central and State level is supposed to ensure quality of drugs. DCGI with the help of the Drug Technical Advisory Board, Drug Consultative Committee is responsible to look into the safety of medicines, as to which drugs need to be restricted or withdrawn, and which new drugs will be allowed to be marketed.

The National List of Essential Medicines has been drawn up by the Health Ministry in 1996 and updated in 2003.

It may be noted that the National Health Policy was formulated in 1983 and 2002.

It is the Chemicals Ministry, which is the nodal ministry for formulating the Pharmaceutical Policy – which was announced in 1978, 1986, 1994 and 2002. Drug prices increased as markups MAPE was increased with each Drug Price Control Order (DPCO) that followed, and number of drugs under price control decreased.

Comparative Chart Summarizing Price Control Scheme under Various Drug Price Control Orders

		DPCO 1979	DPCO 1987	DPCO 1995	Present Oct. 2003
1	No. of drugs under Price Control	347	142	76	74
2	No. of categories under which the above drugs were categorised	3	2	1	1
3	MAPE % allowed on normative/ National exfactory costs to meet Post-manufacturing expenses and to Provide for margin to the Manufacturers				
	Category I	40%	75%	100%	100%
	Category II	55%	100%	N.A.	
	Category III (Single ingredient Leader products)	100%	N.A.	N.A.	
4	Total Domestic pharma sales covered under Price-Control (Approx.)	90%	70%	50%	-

Source: Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India, Locost, Vadodara, 2004.

It was because of well intentioned inverse drug pricing, to ensure that essential drugs for National Health Programme were reasonably priced and profits were made from other drugs outside price control, which allowed the least 'mark up' for the essential drugs under **Category I i.e. drugs for National Health Programme** as compared to **Category II i.e. other essential drugs**, with all other drugs being out of price control that production of Category I drugs decreased and drugs outside price control started increasing.

Kelkar Committee* reviewing **Category II** drugs for the formulation of the drug policy following representation from rational drug campaigners recognized the implications of making irrational and non essential drugs outside the price control more profitable, and the need for uniform mark up, so that there was an incentive to produce essential drugs and curtailing of the profitability of non-essential drugs, irrational drugs – many of which should not be allowed to be in the market in the first place.

The aspects of drug production and drug pricing are handled by Chemicals Ministry.

Hathi Committee in 1978 had recommended the formation of the **National Drug Authority**, which was also recommended in the 1986 and 1994 drug policy. Its formation is still due.

The 1994 drug policy had also recommended formation of the **National Pharmaceutical Pricing Authority** under the Chemicals Ministry, which has been set up and has been functioning. Its role is to fix and monitor drug prices. The legal instrument under which this is done is the Drug Price Control Order.

The industry has been pushing for further decontrol and deregulation, in keeping with the changes in economic policies towards liberalization, privatization and globalization. This market orientation at the cost of public health and public interest, is reflected in every policy – economic, industry, agriculture and even in health policies.

The 1995 World Health Report 'Bridging the Gap', had included a new category in the International Classification of Diseases (ICD) Z 59.5, which stood for "Extreme Poverty". The report said extreme poverty was increasing worldwide and so are the inequalities between the northern and southern countries and between rich and poor within countries.

UNDP reports have also indicated clearly and repeatedly the increasing economic, social and gender inequalities. The control on resources and decision making in the hands of few, to benefit themselves and their cronies, with little or no accountability, is the reflection of the trend of market oriented economic growth, without concern for equity and sustainability and at the cost of people.

This jobless growth, casualization of labour, along with systematic asphyxiation of traditional livelihoods, havoc in the agriculture sector as reflected by suicides of thousands of farmers and migration to

city slums and other states for any work, disrupting families and social fabric clearly means that a large number of people do not have the purchasing power to buy adequate food nor medicines. This is the social reality for a large number of Indians.

With almost 80% health care in private hands and further move towards privatization, public private partnerships, fee for service, it is evident that the issue of affordability of medicine and medical care for those below and around poverty line, those with the highest disease burden and those most vulnerable, it is and it will be a question of life and death, suffering or relief.

The 'right to essential drugs' is part of the 'right to health' campaign and is being undertaken by health, consumer, women groups and in the area of AIDS by anti-AIDS activists.

Access to medicine includes issue of **affordability**. **Essential and life saving drugs even if produced, if they are unaffordable to those who need them the most, it would actually mean denying them access.**

It is a pity that it is not the public health priorities that guide the pharmaceutical companies and other agencies involved in health. For industry it is a trade issue with profit orientation as it is also for the retailers, distributors, dispensers and even prescribers. But those involved with health, strongly believe that public health priorities should guide this work.

The issue of affordability of drugs is a burning issue, where majority of the people are concerned.

Medical indebtedness due to medical reasons has emerged as the second commonest cause of rural indebtedness, according to NCAER report.

There has been a drastic increase in prices of many medicines, with no increase in incomes, infact with loss of employment, denial of treatment or increase in indebtedness can be expected.

It was the protests by anti-AIDS, drug and health activists at WHA, Doha, at Cancun that focussed attention on the outrageous drug prices of anti-AIDS drugs by the patent holders annual treatment cost with anti-retroviral drugs was $15,000/year, when the generic equivalents were available at less than one tenth $ 650/year and further reduced to $ 350/per year treatment offered by Cipla.

Bilateral pressure and pressure of TRIPS did not allow the use of compulsory licensing and parallel import, the available TRIPS safeguards in some countries. With 39 pharmaceutical companies challenging South African government in court for wanting to make anti retroviral drugs available to its people using compulsory licensing, with the same happening in the case of Brazil, where US took Brazil to WTO Dispute Settlement court for the same. There is a deep concern in public health minded organizations that bilateral pressures and threat and fear of TRIPS violation, real or imaginary are forcing

** Kelkar Committee under the Chairmanship of Dr Vijay Kelkar the then Chairman of BICP, reviewed Drug Pricing and Category II Drugs in 1987.*

developing countries to change their own patent laws which will create problems regarding "access" and affordability of drugs in the future.

The TRIPS draft was formulated by Trade Associations of US, Europe and Japan many of them being giant pharma corporations.

This was presented to the GATT Secretariat and then to the world as a GATT secretariat document. Prior to the 8th round of GATT called the Uruguay Round in 1988 when TRIPS, agriculture and services were brought into the ambit of GATT, Intellectual Property Rights issue were dealt by World Intellectual Property Organization, agriculture by Food & Agriculture Organization and trade by Unctad etc.

Numerous protests were held but ultimately the 'Dunkel Draft' text was accepted by our government, where the only choice offered was to 'take it or leave it' i.e. 'all or none' with no scope for any modifications incorporating the concerns of the developing countries. This was done amidst a calculated but cleverly cultivated atmosphere, where the policy makers and the public, became victims of the extremely disempowering TINA syndrome. **There Is No Alternative**. It is well known that decision of the powerful are always in their own interest, to protect their power and to increase their power. The WTO exemplifies this, unlike in UN system with one country one vote, the decisions in WTO are taken in the green room by a handful of powerful countries in a total lack of TRANSPARENCY. The total delinking with the effect and consequences of these decisions further reflects **'appropriation of power without accountability'**. With all other treaties and agreements being made sub servient to WTO, the poor specially those in the developing countries have been made more vulnerable – with these inequality creating, poverty creating, international regimes forcing national policy changes on an unwilling public. The decisions were top down, bulldozed hurriedly without due time for understanding implications. The changes in the Indian Patent Act, the lifting of quantitative restrictions are such examples.

Doha Declaration September 2001 was made under public pressure and pressure from developing countries to protect public health priorities, while TRIPS and other regimes were being pushed on them. Having very unwillingly signed the Doha Declaration by powerful nations led by US, attempts were made to sabotage it.

First an effort was made by US to restrict the definition of public health to only 3 diseases HIV/AIDS, TB and malaria. This was followed by a systematic propaganda about poor quality of Indian drugs.

The price difference was stated to be due to differences in quality and bio-availability. This was precisely the argument given by US manufactures of anti-retroviral drugs for AIDS, for justifying their high drug costs for their drugs being so much more costly than the much cheaper generic equivalents from India – which have been certified as quality drugs by WHO, by creating doubts about quality of Indian drugs for their own economic advantage. Delegitimization of

the legitimate so as to appropriate is well known, here it was the attempt at appropriation of the export markets of these developing countries to the LDC's, with little or no manufacturing capability.

There is a significant pressure to remove the Drug Price Control Order. Infact at the time of signing the TRIPS Agreement/WTO by Commerce Secretary (with unfortunately health authorities not being significantly in the picture, to safeguard the public health interest nor any significant public debate), it was said that the concern about 'access' and 'over pricing' due to monopoly control for 20 years, was unfounded, as it would not affect us as we had the Drug Price Control Order (DPCO) as a tool to curtail overpricing. The TRIPS Agreement has been signed and WTO came into force in 1995. The TRIPS regime for India with product patent comes into force in January 2005. Instead of 5-7 years, the patent period increases to 20 years, from process patent it shifts to product patent regime.

Later in Geneva at August 2003 end just prior to Cancun decision were taken on the long pending para 6 of TRIPS agreement about sales of drugs to Least Developed Countries with no manufacturing capabilities – that parallel import was allowed from countries such as India, but with conditionalities such as different shape, size, colour of medicines for export, time limit, prior information to the TRIPS council, putting information on website about batch, size, duration etc. This was done to create hurdles and block exports of cheaper generic equivalents from developing countries which sell much cheaper yet quality drugs.

Comparison of International Prices vis-à-vis Indian Prices: Some Selected Products
Retail Prices in India & wholesale prices in other countries considered

Drugs, Dosage & Pack	*Prices in India (Rs.)*	*Prices in Pakistan (Rs.)*	*Prices in Indonesia (Rs.)*	*Prices converted into Indian Rs.*	
				Prices in UK (Rs.)	*Prices in USA (Rs.)*
Anti infective Ciprofloxacin HCL 500 mg 10's tabs	29.00	423.86	393.00	1185.70	2352.35
Times Costlier		**14.55**	**13.55**	**40.89**	**81.12**
Norfloxacin 400 mg 10's tabs	20.70	168.71	130.63	304.78	1483.66
Times Costlier		**8.15**	**6.13**	**14.72**	**89.06**
Ofloxacin 200 mg 10's tabs	40.00	249.30	204.34	818.30	1973.79
Times Costlier		**6.23**	**5.10**	**20.45**	**49.34**
Anti-Ulcer Diclofenac Sodium 50 mg 10's tabs	3.50	84.71	59.75	60.96	674.77
Times Costlier		**24.20**	**17.07**	**17.42**	**192.79**

Drugs, Dosage & Pack	*Prices in India (Rs.)*	*Prices in Pakistan (Rs.)*	*Prices in Indonesia (Rs.)*	*Prices converted into Indian Rs.*	
				Prices in UK (Rs.)	*Prices in USA (Rs.)*
Rantidine 150 mg 10's tabs	6.02	74.09	178.35	247.16	863.59
Times Costlier		**12.31**	**29.63**	**41.06**	**143.45**
Omeprazole 30 mg 10's caps	22.50	578..00	290.75	870.91	2047.50
Times Costlier		**25.58**	**12.92**	**38.71**	**91.00**
Cardiovasculars					
Atenolol 50 mg 10's tabs	7.50	71.82	119.70	NA	753.94
Times Costlier		**9.58**	**15.96**	-	**100.52**
Amlodipine Besylate 5 mg 10's tabs	7.80	200.34	78.42	338.28	660.21
Times Costlier		**25.68**	**10.05**	**43.37**	**84.64**
Anti-histamine					
Ceterizine 10 mg 10's tabs	6.00	35.71	57.50	262.19	927.29
Times Costlier		**5.95**	**9.58**	**43.70**	**154.55**
Anti-Anxiolotics /Psychotics					
Alpramazol 0.5 mg 10's tabs	7.00	160.57	31.05	NA	446.81
Times Costlier		**22.94**	**4.43**		**63.83**
Anti-Cancer					
Boposide 100 mg injection	190.00	554.69	242.90	1217.43	6210.30
Times Costlier		**2.92**	**1.28**	**6.41**	**32.68**
Antiasthmatic					
Salmeterol 25 mcg Fluticasone 50 mcg inhaler	210.00	NA	782.65	1628.25	NA
Times Costlier		-	**3.73**	**7.75**	-
Urology					
Sildenafil Citrate 50 mg 4's tabs	48.00	NA	1356.93	1614.89	1744.93
Times Costlier		-	**28.26**	**33.64**	**36.35**

Source: B.K. Keayla, Convenor, National Working Group on Patent Laws, 2004.
Conversion Rate of Exchange considered
USD = Rs. 45.50, 1 GBP = Rs. 83.51 PAK, Rs. = 0.84, 1 Indonesian Rp = Rs. 0.005
Source for Prices: USA Prices – Red Book 2002
UK Prices – UK MIMS Feb. 2004
Pakistan – Pharmaguide June 2002-03
India – IDR Nov./Dec. 2003

The Indian Patent Act 1970 has been amended twice, in 1999 and in 2002.

Before TRIPS comes into force in December 2004 the 3rd amendment of the Indian Patent Act 1970 will be brought in to force to comply with TRIPS and WTO, after clearance from the Parliament.

TRIPS review which was to take place in 2000 is still pending. It must take place before any amendments are made.

The existing safeguards must be optimally used and definitions be put unambiguously e.g. of invention, discovery, public health etc. and criteria for patentability, so that patents for frivolous claims, dosage forms, combinations etc. are not granted and it is only for molecules. Health groups have also asked for **no patents on life**.

It has also been found that prices of combination drugs as compared to single ingredient drugs are also much higher, with no significant therapeutic advantage.

The Drug Price Control Order being the only tool to prevent overpricing, it must stay in place and drug prices need to be monitored closely.

The President's address in the Parliament and the Common Minimum Programme of the new UPA government both make statements about making affordable drugs available.

The SLP filed in the Supreme Court in January 2004 by AIDAN, MFC, LOCOST and JSS regarding affordability of drug prices and access to essential drugs, addresses these public health concerns.

Consequences of High Drug Prices and Unaffordability

1. Needless, preventable, deaths.
2. Complications and disability because of non-availability of medicines.
3. Spread of diseases–specially communicable diseases, outbreaks, epidemics.
4. Irregular treatment and default in treatment i.e. purchase of medicines only when money is available– resulted in emergence of drug resistance in communicable diseases.
5. Further denial to the vulnerable sections of society i.e. the poor, the women, elderly, disabled and children suffer the most.
6. Taking of loans – increasing medical indebtedness, or destitution.
7. Absenteeism, decreased productivity of work force.
8. Perpetuation of spurious counterfeit drug market, making cheap, fake, affordable drugs available to ignorant public, which desperately needs them.

There is a need to control drug prices because:

1. Drug prices are controlled in most countries directly or indirectly either through National Health System or by the Health Insurance Companies by restricting the list of drugs that can be prescribed, and by monitoring prescriptions and prices.

2. Significant percentage of our people are poor and while drug costs constitute a mere 7% of the health care costs in US, it is about 50% of the health care cost in India.
3. The extent of unemployment, underemployment is a serious issue and the incomes are low and therefore purchasing power is low.

Our drugs are relatively cheaper because of the following reasons:

1. We have around 20,000 manufacturers unlike in many countries, because of Indian Patent Act 1970 i.e. adequate competition, with some drugs being manufactured by several manufacturers under different brands, unlike in countries facing perpetual shortage and dependence on imports.
2. The reason for drug prices to be lower than in the West is due to purchasing power in the West because of higher remuneration (to buy 10 tablets of paracetamol an unskilled person in US, UK would have to work 10 minutes, but in India about 60 minutes making the drug 600% more costly).
3. We have a large population and therefore we have 'economy of scale', in drug production i.e. larger production and sales are always cheaper lower cost, because of cheaper skilled and semi skilled manpower, unlike in many countries where it is not cost effective to produce certain drugs but rather import it.
4. Drugs are costly in other countries when royalty has to be paid to patent holder. These countries without manufacturing capability have to import drugs and pay custom duties for imported drugs in addition to sales tax, excise duty etc. have to be paid. With large manufacturing base in India due to IPA 1970 (Indian Patent Act) we did not have to pay royalty and custom duties. However things will change with TRIPS coming into force in 2005 with the coming of the product patent regimes.
5. Qualified pharmacists staff man the pharmacies and drug stores. Many of the chemist shops in India are set up without authorization in the name of pharmacists that are absent, cutting costs (labour costs are much less with availability of skilled and semi skilled workers).

We need price control because competition does not necessarily regulate the market. There are tremendous differences in the different brands of the same drug.

Striking Variations (2-20 Times) in Prices of Branded Drugs

Drug dose	*Strength, unit*	*Use of drug*	*Price variation: (Highest/Lowest) x 100*
Albendazole	400 mg, 1 tab	Treatment of worms	212%
Amoxicillin	500 mg, 1 cap	Useful antibiotic	250%
Cefotaxine*	1 gm, 1 vial	Antibiotic for serious infections, incl. Hospital acquired infections	287%*
Ciprofloxacin*	500 mg, 1 tab	Typhoid fever, urinary infections	294%*
Ethambutol	800 mg, 1 tab	Tuberculosis	325%
Doxycycline	100 mg, 1 cap	Cholera, genitourinary infections	400%
Azithromycin	250 mg, 1 cap	Genitourinary infections	460%
Ceftriaxone	1 gm, 1 vial	Antibiotic for typhoid, gonorrhea	426%
Zidovudine	100 mg, 1 tab	Treatment of HIV/AIDS	669%
Cefuroxine axetil	250 mg, 1 tab	Antibiotic for resp. infections, cheaper alternatives exist	694%
Amlodipine	5 mg, 1 tab	Treatment of Hypertension	962%
Tamoxifen	10 mg, 1 tab	Treatment of breast cancer	1227%
Cycloserine	250 mg, 1 tab	Drug resistant tuberculosis	1488%
Fluconazole	150 mg, 1 tab	Fungal infections	2133%

Source of information: Current Index of Medical Specialties, July 2003.
Drugs marked with asterisk are under price control as per provisions of DPCO 1995.

While some price difference due to better packaging etc. may be possible but drastic price differences, is questionable. The margins between generic medicine and retails are evident in the following table.

Cost Differences			
	Name of the Drug & Manufacturer	*Cost*	*Price difference as a%Between the highest and the lowest*
1.	Fexotenadine 120 mg		
	Almex (Dabur)	Rs 5 per tab	60%
	Allegra Hoechst	Rs 8 per tab	
2.	Gliclazide (10 tabs)		
	Glidiet (Modi Mudhu Pharma)	Rs 31	90%
	Dia Micron (Serdia)	Rs 59	
3.	Ofloxacin (10 tabs)		
	Oftin (Cadila Health care)	Rs 100	530%
	Tarivid (Aventis)	Rs 530	
4.	Risperidone		
	All manufacturers	Rs 18	750%
	Johnson & Johnson	Rs 135	
5.	Amlodipine (10 mg 10 tabs)		
	Amlodac	Rs 14	250%
	Amlovas	Rs 35	

Source: Dr C.M. Gulhati.

There are dramatic differences in the drug costs quoted in the tenders submitted and in the retail market. The following table shows this telling difference between the quoted tender price to TN State medical and retail pricing.

A Comparison of Tender Rates and Retail Market Rates

Sl. No.	*Drug Name*	*Name of Firm*	*Tender Rate (Rs)*	*Unit*	*Manufacturer*	*Retail Market Price (Rs)*	*Overprice Index Col (6)/(3)*
1	Albendazole Tab IP 400 mg	Cadila Pharmaceuti-cals P. Ltd.	22.6	10x10 tablets	Torrent	1190	52.65
2	Bisacodyl Tab IP (I) Ltd. 5 mg	Lark Laboratories	16.5	10x10 tablets	German Remedies	717	43.45
3	Alprazolam Tab IP 0.5 mg	Bal Pharma Ltd.	3.5	10x10 tablets	Sun Pharma	141.5	40.43
4	Diazepam Tab IP 5 mg	Pharmafabricon /LOC OST	3.05	10x10 tablets	Ranbaxy	92.5	30.33
5	Folic acid and Ferrous Tab NFI	Aurochem India P Ltd.	5.89	10x10 tablets	Smith Kline	148.5	25.21
6	Amylodipine Tab 2.5 mg	Lark Laboratories (I) Ltd.	9.1	10x10 tablets	Lyka	148.5	16.32

Excerpted from: Srinivasan, S. "How Many Aspirins to the Rupee? Runaway Drug Prices", Economic and Political Weekly, February 27 – March 5, 1999.

Shocking Margins – A Sample Comparison of Generic Medicine Prices and Retail Prices

No.	*Name of Drug*	*Strength*	*Use*	*LOCOST*, Baroda Price June-Sept. 2003*	*MRP of Standard Company as per DRUG TODAY*** April-June 2003
1.	Albendazole Tabs	400 mg	Against worm infestation	Rs. 11.00 per strip of 10 Tabs	Rs. 9.00 per Tab (strip of 1 Tab)
2.	Amlodipine Tabs	5 mg	Anti hyper-tensive (for high BP)	Rs. 2.50 per strip of 10 Tabs	Rs. 21.77 per strip of 10 Tabs
3.	Amoxycillin Capsules	500 mg	Antibiotic	Rs. 19.75 per strip of 10 Tabs	Rs. 68.60 per strip of 10 Caps

4.	Atenolol Tablets	50 mg	Anti hyper-tensive (for high BP)	Rs. 2.80 per strip of 14 Tabs	Rs. 20.00 per strip of 14 Tabs
5.	Enalapril Maleate	5 mg	Anti hyper-tensive (for high BP)	Rs. 3.00 per strip of 10 Tabs	Rs. 22.58 per strip of 10 Tabs
6.	Fluconazole Capsules	150 mg	Antifungal	Rs. 35.00 per strip of 10 Caps	Rs. 29.50 per caps (strip of 1 Cap)
7.	Glibenclamide Tablets IP	5 mg	Anti-diabetic	Rs. 1.50 per strip of 10 Tabs	Rs. 3.73 per strip of 10 Tabs
8.	Metformin Tablets	500 mg	Anti-diabetic	Rs. 3.00 per strip of 10 Tabs	Rs. 6.45 per strip of 10 Tabs
9.	Paracetamol Tabs –500 mg	500 mg	Fever reducing	Rs. 2.00 per strip of 10 Tabs	Rs. 6.90 per strip of 10 Tabs
10.	Rifampicin Capsules	450 mg	Anti-TB	Rs. 32.00 per strip of 10 Caps	Rs. 59.12 per strip of 10 Caps.

**from LOCOST Price List (June-Sept. 2003).*
***from DRUG TODAY (April-June 2003).*
Source: Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India, Locost, Vadodara, Gujarat, India.

It is also unfortunate that it is the costly, most aggressively marketed drugs that tend to capture the market. See the following examples. Anti retroviral, anti AIDS drugs once started have to be taken life long. Same is for anti-diabetic and anti-hypertensive drugs unlike anti-TB and malaria drugs.

	Annual Treatment Cost	***Total Sale***
Glicazide – anti-diabetic drug which is to be taken life long		
Glidiet (Modimundi Pharma) Diamicron (Serdia)	10 tab Rs 30 10 tab Rs 59	Rs 66 lac Rs 7 crore
Acylovir Anti AIDS Drug		
Cyclovir (Zydus) Herpex (Torrent)	Rs 812 Rs 922	Rs 57 lac Rs 3.17 crore

IFPMA (International Federation Pharmaceutical Manufacturers Association) and WHO Code for ethical marketing practices exists, yet it is often known to be violated with seldom any action being taken against the violators.

Dr C.M. Gulhati in his article 'Drug Price Control: principles, problems and prospects gives examples of how annual free trip to Switzerland paid for by a pharma company has

resulted in special increase in the prescription of the company products, and where antibiotics are concerned their being prescribed for 10 days rather than the normally accepted 5-7 days course.

Sponsoring a 3-day stay in Singapore with spouses by Johnson and Johnson of 300 kidney specialists to attend a "3 hour scientific conference" has resulted in its product Epoetin alfa – a life saving drug for patients who have undergone kidney transplants – having the highest sales.

Medical doctors are taught pharmacology but not Rational Drug Use in medical education, where they can be equipped to make rational choices about medicines they prescribe and be sensitive about the relative cost of drugs, from the same therapeutic category and also about the socio-economic status and purchasing power of their patients.

Dr.Gulhati also expresses his concern regarding choice of drugs, this could be due to lack of clear therapeutic guidelines, as well as due to aggressive detailing by sales representatives. Therefore prescriptions are often **scientifically inappropriate and financially costly**.

Chlamydial genital infection can be treated by tetracycline for Rs 14, yet most prescriptions are for Oflaxacin costing Rs. 70-380.

When there is no difference in therapeutic efficacy of proton pump inhibitors to decrease gastic secretion with Omeprazole costing Rs 40 for 10 tablets and Pantoprazole Rs 65 for 10 tablets. Most prescriptions are for the costly pantoprazole

Anti hypertensive drug Enalapril costs Rs 10.50 per 10 tabs and Perinidopril costs Rs 100 for 10 tabs

Yet it is the costlier drug that is more prescribed.

Different Prices of Amlodipine – anti hypertensive

Drug	*Brand Name*	*Company*	*Price per tablet of 5 mg*
Amlodipine 5 mg	Amlogard	Pfizer	Rs. 4.81
Amlodipine 5 mg	Stamlo	Dr. Reddy's	Rs. 2.47
Amlodipine 5 mg	Amlogen	Alkem	Rs. 1.20
Amlodipine 5 mg	Amlodac	Alidac	Rs. 0.50

Source of Prices: April-June 2002 edition of CIMS

Different Prices of Ceftriaxone

Drug	*Brand Name*	*Company*	*Price per 1 g*
Inj. Ceftriaxone	Cefaxone	Lupin	Rs. 213
Inj. Ceftriaxone	Oframax	Ranbaxy	Rs. 99
Inj. Ceftriaxone	Gutencef	E-merck	Rs. 50

All prices are as mentioned in the April-June 2002 edition of CIMS.

Source: All the tables taken from Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India, Locost, Vadodara, Gujarat, India.

Cost of Some Antiretrovirals in India

Drug	*Cost per Tab.*	*Dose per Day*	*Cost of Rx per Day*
Zidovudine	Rs 12 for a 100 mg tab.	200 mg 8 hourly	Rs. 72
Lamivudine	Rs. 30 for a 150 mg tab.	150 mg 12 hourly	Rs. 40
Nevirapine	Rs. 39 for a 200 mg tab.	200 mg per day	Rs. 39
Lamivudine + Zidovudine	Rs. 51 for a tab.	1 tab. 12 hourly	Rs. 100

Note: Prices of CIPLA products as quoted in CIMS, July 2003.

Dr C.M.Gulhati expresses his legitimate concern that if few drugs from a certain therapeutic category are price controlled, drug promotion and prescription ** will shift to other drugs as has already happened in the past.

If chloroquine 60 paisa per tablets is price controlled prescriptions will shift to mefloquin or artemether Rs 14 per tablet. Both the above are reserved drugs for chloroquine resistant malaria patients. They should not be used as first line drug.

Price control of ranitidine used for peptic ulcer will result in shift to other H_2 receptors antagonists like famodine, omeprazole.

Cough and cold remedy is an international brand Actifed by Glaxo contains pseudoephedrine all over the world except India where it contains Phenyl Propanolamine (PPA) which has been found to be associated with strokes 2 years ago. Coldarin another cough and cold, over the counter(OTC) brand proudly proclaimed in front page advertisement that coldarin was free from PPA – yet it has reverted to PPA because it is cheaper and pseudo ephedrine also a decongestant is under price control.

Chronic peptic ulcer pain has been found to be associated with H-pylori infection and unlike treatment of ordinary peptic acid disease treatment with ant acid, here 3 categories of drugs are required:

Proton Pump inhibitor		Omeprazole
	Or	Lansoprazol
	Or	Pentaprozole
Antibiotic		Amoxycillin
	Or	Clarithromycin
	Or	Oxytetra cycline
Imidazole		Metronidazole
	Or	Tinidazole
	Or	Secnidazole

Price control of only 1 drug from each category will unfortunately become meaningless because prescriptions will shift to the uncontrolled more profitable drugs.

There are many anti cancer drugs that are outrageously priced and unaffordable when it comes to completion of the chemotherapy course for a significant number of people needing medical care. Treatment for non-communicable diseases, diabetes, hypertension, HIV/AIDS are required life long.

It is also important to remember that if drugs for communicable diseases are not used rationally – avoiding drug default because of non-affordability as has been seen with anti-TB drugs. Drug resistance which is already taken as a major public health problem will worsen. The drugs required when this happens are further unaffordable, and the tragedy is that, if untreated, the further spread and outbreaks would be with drug resistant organisms, resulting in outbreaks, epidemics and deaths.

Drugs for diseases of poverty are not a priority for pharma and the cutting back of public sector resources is well known. The last anti-TB drug was discovered 28 years ago.

Comparative Prices of Chloroquine vs. Alternative Drugs Required in Treatment of Chloroquine Resistant P.Falciparum Malaria

Drug	*Cost per tab.*	*Cost per inj*
Chloroquine	Rs. 0.90 for a 250 mg tab	Rs. 3.46 for 200 mg
Quinine	Rs. 5.00 for a 300 mg tab	Rs. 18.00 for 600 mg
Artesunate	Rs. 22.00 for a 60 mg tab	Rs 162.00 for 60 mg

Source: CIMS July 2003.

Comparative Costs of Treatment of P.Falciparum Malaria Using Different Drugs

Oral chloroquine	Rs. 10
Oral quinine	Rs. 210
Inj. Artesunate	Rs. 972

Ref.: CIMS, July 2003.

Costs of Drugs Used in Management of Drug Resistant Tuberculosis

Drug	*Price per tablet*	*Cost of Rx per day*
Ethionamide	Rs 13.00 for 250 mg	Rs 26-52 for 0.5 g – 1.0 g/day
Ofloxacin	Rs 4.00 for 200 mg	Rs 12-16 for 600-800 mg/day
Amikacin	Rs 60.00 for 500 mg	Rs 90-120 for 750 mg/day
Capreomycin	Rs 204.00 for 0.75 mg	Rs 204-275 for 0.75-1g/day
Cycloserine	Rs 30.00 for 250 mg	Rs 60-90 for 0.5-0.75 g/day
Prothionamide	Rs 15 for 250 mg	Rs 30-45 for 0.5-0.75 g/day

Ref.: CIMS, July 2003.

Source: All the tables in this chapter are taken from Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India, Locost, Vadodara, Gujarat, India.

Drugs must be rationally, specially antibiotics drugs needed if resistance emerges are unaffordable.

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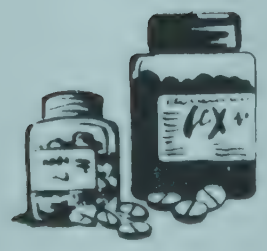
SLC filed by AIDAN, MFC, Locost and JSS submitted to the Hon'ble Supreme Court of India in the case of SPL No.3668 of 2003 in the matter of Union of India Vs K.S. Gopinath & Others and would be subject to the final direction given by Hon'ble Court in the matter."



Annexure I

NATIONAL LIST OF ESSENTIAL MEDICINES 2003

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
1.	**Anaesthetics**			
1.1	General Anaesthetics and Oxygen	S,T	Inhalation	
	Ether, Anaesthetic	S,T	Inhalation	
	Halothane	S,T	Inhalation	
	Isoflurane*	U	Injection	10 mg/ml 50 mg/ml
	Ketamine Hydrochloride	U	Inhalation	
	Nitrous Oxide	U	Inhalation	
	Oxygen	U	Inhalation	
	Thiopentone Sodium	S,T	Injection	0.5 g, 1 g power
1.2	Local Anaesthetics			
	Bupivacaine Hydrochloride	S,T	Injection	0.25% 0.5% 0.5%+ 7.5% Glucose
	Ethyl Chloride	U	Spray	1%
	Lignocaine Hydrochloride	U	Topical Forms Injection	2-5% 1-2% 5%+ 7.5 Glucose
	Lignocaine Hydrochloride + Adrenaline	U	Injection	1%, 2%+ Adrenaline 1:200,000 In vial

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
1.3	Preoperative Medication and Sedation for Short Term Procedures			
	Atropine Sulphate	U	Injection	0.6 mg/ml
	Diazepam	U	Tablets / Injection	5 mg 5 mg
	Midazolam	U	Injection	1 mg / ml 5 mg / ml
	Morphine Sulphate	S,T	Injection	10 mg / ml
	Promethazine	U	Syrup	5 mg / 5 ml
1.4	Postoperative Respiratory Stimulant			
	Doxapram*	T	Injection	4 mg / ml
2.	**Analgesics, Antipyretics, Nonsteroidal Anti-inflammatory Medicines, Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders.**			
2.1	Non-Opioid Analgesics, Antipyretics and Nonsteroidal Anti-inflammatory Medicines			
	Acetyl Salicylic Acid	U	Tablets	300-350 mg
	Diclofenac	T	Tablets	50 mg 100 mg 25 mg/ml
	Ibuprofen	U	Injection	200 mg 400 mg
	Paracetamol	U	Injection Syrup Tablets	150 mg / ml 125mg/5ml 500 mg
2.2	Opioid Analgesics			
	Morphine Sulphate	S,T	Injection Tablets	10 mg/ml 10 mg
	Pentazocine	S,T	Tablets Injection	25 mg 30 mg/ml

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Pethidine Hydrochloride	S,T	Injection	50 mg/ ml
2.3	Medicines used to treat Gout			
	Allopurinol	S,T	Tablets	100 mg
	Colchicine	S,T	Tablets	0.5mg
2.4	Disease Modifying Agents used in Rheumatoid Disorders			
	Azathioprine	S,T	Tablets	50 mg
	Chloroquine Phosphate	S,T	Tablets	150 mg
	Methortrexate	S,T	Tablets	2.5
	Sulfasalazine			
3.	**Antiallergics and Medicines used in Anaphylaxis**			
	Adrenaline Bitartrate	U	Injection	1 mg/ml
	Chlorpheniramine Maleate	U	Tablets	4 mg
	Dexchlorpheniramine Maleate		Syrup	0.5 mg / 5 ml
	Dexamethasone	U	Tablets Injection	0.5 mg 4 mg/ml
	Hydrocortisone Sodium Succinate	U	Injection	100 mg
	Pheniramine Maleate	U	Injection	22.75 mg / ml
	Prednisolone	S	Tablets	5 mg
	Promethazine	U	Tablets Syrup	10 mg. 25 mg 5 mg / ml

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
4.	**Antidotes and Other Substances used in Poisonings**			
4.1	Nonspecific			
	Activated Charcoal	U	Powder	
	Atropine Sulphate	U	Injection	0.6 mg / ml
4.2	Specific			
	Antisnake Venom	U	Injection Polyvalent Solution / Lyophilyzed Polyvalent Serum	
	Calcium Gluconate	S,T	Injection	100 mg / ml
	Desferrioxamine Mesylate	S,T	Injection	500 mg / ml
	Dimercaprol	S,T	Injection in oil	50 mg/ml
	Flumazenil*	T	Injection	0.1 mg/ml
	Methylthioninium Chloride (Methylene blue)	S,T	Injection	10 mg/ml
	Naloxone	S,T	injection	0.4 mg/ml
	Penicillamine	S,T	Tablets or capsules	250 mg
	Pralidoxime Chloride (2-PAM)	S,T	Injection	25 mg/ml
	Sodium Nitrite	S,T	Injection	250 mg/ml
	Sodium Thiosulphate	S,T	Injection	250 mg/ml
5.	**Anticonvulsants/Antiepileptics**			
	Carbamazepine	U	Tablets Syrup	100mg 200 mg 20 mg/ml
	Diazepam	U	Injection	5 mg/ml
	Magnesium Sulphate	T	Injection	500 mg/ml
	Phenobarbitone			

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Phenytoin Sodium	U	Capsules or Tablets	50 mg, 100 mg
			Syrup	25 mg/ml
			Injection	50 mg/ml
	Sodium Valproate	U	Tablets	200 mg, 500 mg
			Syrup	200 mg/5ml
6.	**Antiinfective Medicines**			
6.1	Anthelminthics			
6.1.1	Intestinal Anthelminthics			
	Albendazole	U	Tablets	400 mg
			Suspension	200 mg/ 5 ml
	Mebendazole	U	Tablets	100 mg
			Suspension	100 mg/5ml
	Niclosamide	U	Chewable Tablets	500 mg
	Pyrantel Pamoate	U	Tablets	250mg
			Suspension	250 mg / 5 ml
6.1.2	Antifilarials			
	Diethylcarbamazine Citrate	U	Tablets	50 mg
6.1.3	Antischistosomals and Antitrematode Medicines			
	Praziquantel	S,T	Tablets	600 mg
6.2	Antibacterials			
6.2.1	Beta Lactam Medicines			
	Amoxicillin	U	Powder for suspension	125 mg / 5 ml
			Capsules	250 mg
				500 mg
	Ampicillin	U	Capsules	250 mg
				500 mg
			Powder for suspension	125 mg/5 ml
			Injection	500 mg

Medicine	Category	Route of Administration/ Dosage Form	Strengths
Benzathine Benzylpenicillin	U	Injection	6 lacs, 12 lacs
Benzylpenicillin	U	Injection	5 lacs, 10 lacs unit
Cefotaxime*	S,T	Injection	125 mg, 250 mg, 500 mg
Ceftazidime*	S,T	Injection	250 mg. 1 g
Ceftriaxone*	S,T	Injection	250 mg. 1 g
Cefuroxime*	S,T	Injection	250 mg, 750 mg
Cloxacillin	U	Capsules Injection Liquid	250 mg 500 mg 250 mg 125 mg / 5ml
Procaine Benzylpenicillin	U	Injection	Crystalline Penicillin (1 lac units)+ Procaine Penicillin (3 lacs units)
6.2.2 Other Antibacterials			
Amikacin*	S,T	Injection	250 mg/ 2 ml
Azithromycin*	S,T	Capsules or Tablets Suspension Capsules	100 mg. 250 mg, 500 mg 100 mg/ 5 ml 500 mg
Cephalexin*	U	Syrup Capsules	125 mg/ 5ml 250 mg, 500 mg
Clarithromycin*	S,T	Capsules	500 mg
Chloramphenicol	S,T	Injection	1 g

*Complementary

Medicine	Category	Route of Administration/ Dosage Form	Strengths
	S,T	Suspension	125 mg/ 5 ml
	S,T	Capsules, Tablets	250 mg 500 mg
Ciprofloxacin Hydrochloride	U	Injection	200 mg
Co-Trimoxazole (Trimethoprim + Sulphamethoxazole)	U	Tablets	40+200 mg 80+400 mg
		Suspension	40+200mg/ 5ml
Doxycycline	U	Capsules	100 mg
Erythromycin Estolate	U	Syrup Tablets	125 mg/ 5ml 250 mg, 500 mg
Gentamicin	U	Injection	10 mg/ ml 40 mg/ml
Metronidazole	U	Tablets	200 mg 400 mg
		Injection	500 mg/100ml
Nalidixic Acid	U	Tablets	250 mg 100 mg
Nitrofurantoin	U	Tablets	100 mg
Norfloxacin	U	Tablets	400 mg
Roxithromycin*	S,T	Tablets	50 mg 100 mg
Sulphadiazine*	S,T	Tables	500 mg
Tetracycline	U	Tablets or Capsules	250 mg
Vancomycin Hydrochloride*	T	Injection	500 mg, 1 g
6.2.3 Antileprosy Medicines			
Clofazimine	S,T	Capsules	50 mg, 100 mg
Dapsone	U	Tablets	50 mg, 100 mg

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Rifampicin	U	Capsules or Tablets	150 mg, 300 mg
6.2.4	Antituberculosis Medicines			
	Ethambutol	U	Tablets	200 mg 400 mg 600 mg 800 mg
	Isoniazid	U	Tablets	50 mg, 100 mg, 300 mg
	Ofloxacin*	S,T	Tablets	50 mg, 200 mg 50 mg/5 ml
	Pyrazinamide	U	Tablets	500 mg 750 mg 1000 mg 1500 mg
	Rifampicin	U	Capsules/Tablets	50 mg 150 mg 300 mg 450 mg 100 mg/5ml
	Streptomycin Sulphate	U	Injection	0.75 g, 1g
	Thiacetazone+Isoniazid	S,T	Tablets	150 mg+ 300mg
6.3	Antifungal Medicines			
	Amphotericin B	S,T	Injection	50 mg
	Clotrimazole	U	Pessaries	100 mg 200 mg
			Gel	2%
	Fluconazole	S,T	Capsules or tablets	50 mg 100 mg 150 mg 200 mg
	Flucytosine	S,T	Capsules	250 mg
	Griseofulvin	U	Capsules or tablets	125mg 250mg

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Ketoconazole	S,T	Tablets	200 mg
	Nystatin	U	Tablets Pessaries	500,000 IU 100,000 IU
6.4	Antiviral Medicines			
6.4.1	Antiherpes Medicines			
	Acyclovir*	S,T	Tablets Injection Suspension	200 mg 400 mg 250 mg 500 mg 400 mg/5 ml
6.4.2	Antiretroviral Medicines*			
6.4.2.1	Nucleoside Reverse Transcriptase Inhibitors			
	Didanosine*	S,T	Tablets	250 mg 400 mg
	Lamivudine*	S,T	Tablets	150 mg
	Lamivudine + Nevirapine + Stavudine*	S,T	Tablets	150 mg +200mg+30g
	Lamivudine + Zidovudine*	S,T	Tablets	150 mg +300mg
	Stavudine*	S,T	Capsules	15 mg, 30 mg, 40 mg
	Zidovudine*	S,T	Tablets	100 mg 300 mg
6.4.2.2	Non-nucleoside Reverse Transcriptase Inhibitors			
	Efavirenz*	S,T	Capsules	200 mg 600 mg

*Complimentary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Nevirapine*	S,T	Capsules Suspension	200 mg 50 mg/5ml
6.4.2.3	Protease Inhibitors			
	Indinavir*	S,T	Capsules	200 mg 400 mg
	Nelfinavir*	S,T	Capsules	250 mg
	Ritonavir*	S,T	Capsules	100 mg 400 mg/ml
	Saquinavir*	S,T	Capsules	200 mg
6.5	Antiprotozoal Medicines			
6.5.1	Antiamoebic and Antigiardiasis Medicines			
	Diloxanide Furoate	U	Tablets	500 mg
	Metronidazole	U	Tablets Injection	200 mg 400 mg 500 mg/ 100ml
	Tinidazole	U	Tablets	500 mg
6.5.2	Antileishmaniasis Medicines			
	Amphotericin B	S,T	Injection	50 mg
	Pentamidine Isothionate	S,T	Injection	200 mg
	Sodium Stibogluconate	S,T	Injection	100 mg/ml
6.5.3	Antimalarial Medicines			
6.5.3.1	For Curative Treatment			
	Artesunate	T	Injection	60 mg
	Chloroquine Phosphate	U	Tablets Injection Syrup	150 mg base 40 mg/ml 50 mg/ml
	Primaquine	U	Tablets	2.5 mg,7.5 mg

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Pyrimenthamine	U	Tablets	25 mg
	Quinine Sulphate	U S,T	Tablets Injection	300 mg 300 mg/ml
	Sulfadoxine + Pyrimethamine	U	Tablets	500 mg+25mg
6.5.3.2	For Prophylaxis			
	Chloroquine Phosphate	U	Tablets Syrup	150 mg base 50 ml/5ml
6.5.4	Antipneumocystosis and Antitoxoplasmosis Medicines			
	Co-Trimoxazole (Trimethoprim + Sulphamethoxazole)	U	Tablets Suspension	40+200 mg 80+400 mg 40+200mg/ 5ml
	Pentamidine Isothionate	S,T	Injection	200 mg
	Trimethoprim	U	Tablets	100 mg
7.	**Antimigraine Medicines**			
7.1	For Treatment of Acute Attack			
	Acetyl Salicylic Acid	U	Tablets	300-350 mg
	Dihydroergotamine	S,T	Tablets	1 mg
	Paracetamol	U	Tablets	500 mg
7.2	For Prophylaxis			
	Propranolol Hydrochloride	U	Tablets	10 mg, 40 mg
8.	**Antineoplastic, Immunosuppressives and Medicines used in Palliative Care**			
8.1	Immunosuppressive Medicines			
	Azathioprine*	T	Tablets	50 mg
	Cyclosporine	T	Capsules	10 mg, 25 mg, 50 mg,

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
			Concentrate for injection	100 ml 100 mg/ml
8.2	Cytotoxic Medicines			
	Actinomycin D*	T	Injection	0.5 mg
	Alpha Interferon*	T	Injection	3 million IU
	Bleomycin*	T	Injection	15mg
	Busulphan*	T	Tablets	2 mg
	Cisplatin*	T	Injection	10mg / vial 50mg / vial
	Cyclophosphamide*	T	Tablets Injection	50 mg 200 mg 500 mg
	Cytosine Arabinoside*	T	Injection	100 mg/vial 500 mg/vial 1000mg/vial
	Danazol*	T	Capsules	50 mg, 100 mg
	Doxorubicin*	T	Injection	10 mg, 50 mg
	Etoposide*	T	Capsules Injection	100 mg 100 mg/5ml
	Flutamide*	T	Tablets	250 mg
	5-Fluorouracil*	T	Injection	250 mg/5ml
	Folinic Acid*	T	Injection	3 mg/ml
	Gemcitabine Hydrochloride*	T	Injection	200 mg, 1 g
	L- Asparaginase*	T	Injection	10000 KU
	Melphalan*	T	Tablets	2 mg, 5 mg
	Mercaptopurine*	T	Tablets Injection	50 mg 100 mg/ml
	Methotrexate*	T	Tablets	2.5 mg

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
			Injection	50 mg/ml
	Mitomycin-C*	T	Injection	10 mg
	Paclitaxel*	T	Injection	30 mg/5ml
	Procarbazine*	T	Capsules	50 mg
	Vinblastine Sulphate*	T	Injection	10 mg
	Vincristine	T	Injection	1 mg/ml
8.3	Hormones and Antihormones			
	Prednisolone*	S,T	Tablets Injection	5 mg 20 mg 25 mg (as sodium phosphate or succinate
	Raloxifene*	T	Tablets	60 mg
	Tamoxifen Citrate*	T	Tablets	10 mg, 20 mg
8.4	Medicines used in Palliative Care			
	Morphine Sulphate*	T	Tablets	10mg
	Ondansetron*	S,T	Tablets Injection Syrup	4mg, 8mg 2mg/ml 2mg / 5ml
9.	**Antiparkinsonism Medicines**			
	Bromocriptine Mesylate	T	Tablets	1.25mg, 2.5mg
	Levodopa+Carbidopa	U	Tablets	100 mg+10mg 250 mg+25mg 100 mg+25mg
	Trihexyphenidyl Hydrochloride	U	Tablets	2 mg
10.	**Medicines affecting the Blood**			
10.1	Antianemia Medicines			

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Cyanocobalamin	U	Injection	1 mg/ml
	Ferrous Salt	U	Tablets	Equivalent to 60 mg elemental iron
			Oral solution	25 mg elemental iron
	Folic Acid	U	Tablets	1 mg. 5mg
	Iron Dextran	S,T	Injection	50 mg iron/ml
	Pyridoxine	U	Tablets	5 mg
10.2	Medicines Affecting Coagulation			
	Acenocoumarol*	S,T	Tablets	1mg, 2mg, 4mg
	Heparin Sodium	S,T	Injection	1000 IU/ml 5000 IU/ml
	Menadione Sodium Sulphite	S,T	Tablets	10mg
	Protamine Sulphate	S,T	Injection	10 mg/ml
	Phytomenadione	S,T	Injection	10 mg/ml
	Warfarin Sodium	S,T	Tablets	5mg
11.	**Blood Products and Plasma Substitutes**			
11.1	Plasma Substitutes			
	Dextran-40	U	Injection	10%
	Dextran-70	U	Injection	6%
	Fresh Frozen Plasma*	T	Injection	
	Hydroxyethyl Starch (Hetastarch)	S,T	Injection	6%
	Polygeline	S,T	Injection	3.5%
11.2	Plasma Fractions for Specific Use			

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Albumin	S,T	Injection	5%, 20%
	Cryoprecipitate	S,T	Injection	
	Factor VIII Concentrate*	S,T	Injection	Dried
	Factor IX Complex (Coagulation Factors II,VII, IX, X)*	S,T	Injection	Dried
	Platelet Rich Plasma	S,T	Injection	
12.	**Cardiovascular Medicines**			
12.1	Antianginal Medicines			
	Acetyl Salicylic Acid*	U	Tablets	75 mg 100 mg 350 mg
	Diltiazem	S,T	Tablets	20 mg, 60 mg
	Glyceryl Trinitrate	U	Sublingual Tablets Injection	0.5 mg 5 mg/ ml
	Isosorbide 5 Mononitrate/Dinitrate	U	Tablets	10 mg, 20 mg
	Metoprolol*	U	Tablets Injection	10 mg, 40 mg 1 mg/ml
	Propranolol	U	Tablets Injection	10 mg, 40 mg 1 mg/ml
12.2	Antiarrhythmic Medicines			
	Adenosine*	S,T	Injection	3 mg/ml
	Amiodarone	S,T	Tablets	100 mg, 200 mg, 150mg
	Bretylium Tosylate*	T	Injection	1 mg, 2mg 4 mg/ml
	Diltiazem	S,T	Tablets	30mg/ 60ml
	Diltiazem*	T	Injection	5mg /ml

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Esmolol*	T	Injection	10 mg/ml
	Isoprenaline Hydrochloride*	T	Injection	2mg/ml
	Lignocaine Hydrochloride	S,T	Injection	1%, 2%
	Mexiletine Hydrochloride	S,T	Capsules Injection	50 mg 150 mg 25 mg/ml
	Procainamide Hydrochloride	T	Tablets Injection	250 mg 100 mg/ml
	Quinidine	T	Tablets	100 mg
	Verapamil	S,T	Tablets Injection	40 mg, 80 mg 2.5 mg/ml
12.3	Antihypertensive Medicines			
	Amlodipine	U	Tablets	2.5 mg, 5 mg, 10 mg
	Atenolol	U	Tablets	50mg 100 mg
	Chlorthalidone*	U	Tablets	25 mg 50 mg
	Clonidine Hydrochloride*	S,T	Tablets	100 mg 150 mg
	Enalapril Maleate	U	Tablets Injection	2.5 mg, 5mg 10 mg 1.25 mg/ml
	Losartan Potassium*	S,T	Tablets	25 mg, 50 mg
	Methyldopa	U	Tablets	250 mg
	Nifedipine	S,T	Capsules Tablets Sustained release Capsules or tablets	5mg, 10mg 10mg, 20mg 10 mg, 20 mg

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Propranolol	U	Tablets	10 mg, 40 mg
	Sodium Nitroprusside*	T	Injection	50 mg/5ml
	Terazosin*	S,T	Tablets	1mg, 2mg, 5mg
12.4	Medicines used in Heart Failure			
	Digoxin	S,T	Tablets Injection Elixir	0.25 mg 0.25 mg/ml 0.05 mg/ml
	Dobutamine*	S,T	Injection	50 mg/ml
	Dopamine Hydrochloride	S,T	Injection	40 mg/ml
12.5	Antithrombotic Medicines			
	Acetyl Salicylic Acid	U	Tablets	75 mg, 100 mg
	Heparin Sodium	S,T	Injection	75 mg, 100 mg 5000 IU/ml
	Streptokinase*	S,T	Injection	750,000 IU 15,00,000 IU
	Urokinase*	T	Injection	500,000 IU/ml 10,00,000 IU/ml
13.	**Dermatological Medicines (Topical)**			
13.1	Antifungal Medicines			
	Benzoic Acid + Salicylic Acid	U	Ointment or Cream	6% + 3%
	Miconazole	U	Ointment or cream	2%
13.2	Antiinfective Medicines			
	Acyclovir	S,T	Cream	5%
	Framycetin Sulphate	U	Cream	0.5%
	Methylrosanilinium Chloride (Gentian voilet)	U	Aqueous Solution	0.5%

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Neomycin+Bacitracin	U	Ointment	5 mg+500 IU
	Povidone Iodine	U	Solution or ointment	5 %
	Silver Nitrate	U	Lotion	10%
	Silver Sulphadiazine	U	Cream	1%
13.3	Anti-inflammatory and Antipruritic Medicines			
	Betamethasone Dipropionate	U	Cream/Ointment	0.05%
	Calamine	U	Lotion	
13.4	Astringent Medicines			
	Zinc Oxide	U	Dusting Powder	
13.5	Medicines Affecting Skin Differentiation and Proliferation			
	Coal Tar	U	Solution	5%
	Dithranol*	T	Ointment	0.1-2%
	Glycerin	U	Solution	
	Salicylic Acid	U	Solution	5%
13.6	Scabicides and Pediculicides			
	Benzyl Benzoate	U	Lotion	25%
	Gamma Benzene Hexachloride	U	Lotion	1%
14.	**Diagnostic Agents**			
14.1	Ophthalmic Medicines			
	Lignocaine	S,T	Eye Drops	4%
	Tropicamide	S,T	Eye Drops	1%
14.2	Radiocontrast Media			

*Complementary

Medicine	Category	Route of Administration/ Dosage Form	Strengths
Barium Sulphate	S,T	Suspension	100% w/v 250% w/v
Calcium Ipodate	S,T	Injection	3 g
Iopanoic Acid	S,T	Tablets	500 mg
Meglumine Iothalamate	S,T	Injection	60%w/v (Iodine=280 mg/ml)
Meglumine Iotroxate	S,T	Solution	5-8 g Iodine in 100-250ml
Propyliodone	S,T	Oily, suspension	500-600mg/ml
Sodium Iothalamate	S,T	Injection	70% w/v (Iodine=420 mg/ml)
Sodium Meglumine Diatrizoate	S,T	Injectiion	60% w/v (Iodine conc.= 292 mg/ml 76% w/v (Iodine conc.= 370mg/ml)
15. Disinfectants and Antiseptics			
15.1 Antiseptics			
Acriflavin+Glycerin	U	Solution	
Benzoin Compound	U	Tincture	
Cetrimide	U	Solution	20% (conc. for dilution)
Chlorhexidine	U	Solution	5% (conc. for dilution)
Ethyl Alcohol 70%	U	Solution	
Gentian Violet	U	Paint	0.5%, 1 %
Hydrogen Peroxide	U	Solution	6%

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Povidone Iodine	U	Solution	5%, 10%
15.2	Disinfectants			
	Bleaching Powder	U	Powder	
	Formaldehyde IP	U	Solution	
	Glutaraldehyde	S,T	Solution	2%
	Potassium Permanganate	U	Crystal for solution	
16.	**Diuretics**			
	Furosemide	U	Injection, Tablets	10mg/ml 40mg
	Hydrochlorothiazide	U	Tablets	25mg, 50mg
	Mannitol*	U	Injection	10%, 20%
	Spironolactone	U	Tablets	25mg
17.	**Gastrointestinal Medicines**			
17.1	Antacids and other Antiulcer Medicines			
	Aluminium Hydroxide + Magnesium Hydroxide	U	Tablet suspension	
	Omeprazole	U	Capsules	
	Ranitidine Hydrocholoride	U	Tablets Injection	150mg, 300mg 25 mg/ml
17.2	Antiemetics			
	Domperidone	U	Tablets Syrup	10mg 1mg/ml
	Metoclopramide	U	Tablets Syrup Injection	10mg 5mg/ml 5mg/ml
	Prochlorperazine	U	Tablets	5 mg, 25mg

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Promethazine	U	Tablets Elixir or Syrup Injection	10mg, 25mg 5 mg/ 5ml 25 mg/ml
17.3	Antihaemorrhoidal Medicines			
	Local Anaesthetic, Astringent and Antiinflammatory Medicines	U	Ointment/suppository	
17.4	Antiinflammatory Medicines			
	Sulfasalazine	T	Tablets	500 mg
17.5	Antispasmodic Medicines			
	Dicyclomine Hydrochloride	U	Tablets Injection	10 mg 10 mg/ml
	Hyoscine Butyl Bromide	U	Tablets or Injection	10mg mg/ml
17.6	Laxatives			
	Bisacodyl	U	Tablets / suppository	5 mg
	Isphaghula	U	Granules	
17.7	Medicines used in Diarrhoea			
17.7.1	Oral Rehydration Salts	U	Powder for solution	As per IP
17.7.2	Antidiarrhoeal Medicines			
	Furazolidone	S,T	Tablets Syrup	100 mg 25 mg/5ml
	Loperamide* (Contraindicated for paediatric use)	S,T	Capsules	2 mg
18.	**Hormones, other Endocrine Medicines and Contraceptives**			
18.1	Adrenal Hormones and Synthetic Substitutes			
	Dexamethasone	S,T	Tablets Injection	0.5 mg 4 mg/ml

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Hydrocortisone Sodium Succinate	U	Injection	100 mg/ml
	Methylprednisolone	S,T	Injection	40 mg/ml
	Prednisolone	U	Tablets	5mg, 10mg
18.2	Androgens	T	Capsules	40 mg (as undecanoate)
	Testosterone	T	Injection	25mg/ml (as proportionate)
18.3	Contraceptives			
18.3.1	Hormonal Contraceptives			
	Ethinylestradiol + Levonorgesterol	U	Tablets	.03 mg+ 0.15mg
	Ethinylestradiol + Norethisterone	U	Tablets	0.035mg+1mg
	Hormone Releasing IUD	T	Levenorgesterol Releasing IUD	
18.3.2	Intrauterine Devices IUD containing Copper	U		
18.3.3	Barrier Methods			
	Condoms	U		
18.3.4.	Non Hormonal Contraceptives			
	Centchroman	U	Tablets	30 mg
18.4	Estrogens			
	Ethinylestradiol	U	Tablets	0.01mg, 0.05 mg
18.5	Antidiabetics and Hyperglycaemics			
18.5.1	Insulins and Other Antidiabetic Agents			

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Glibenclamide	U	Tablets	2.5 mg, 5 mg
	Insulin Injection (Soluble)	U	Injection	40 IU / ml
	Intermediate Acting Insulin (Lente/NPH Insulin)	U	Tablets	40 IU / ml
	Metformin	U	Tablets	500 mg
18.5.2	Hyperglycaemics			
	Glucagon*	T	Injection	1 mg/ml
18.6	Ovulation Inducers			
	Clomiphene Citrate*	T	Tablets	25mg, 50mg 100 mg
18.7	Progestogens			
	Medroxy Progesterone Acetate	U	Tablets	5 mg, 10 mg
	Norethisterone	U	Tablets	5 mg
18.8	Thyroid and Antithyroid Medicines			
	Carbimazole	S,T	Tablets	5 mg, 10 mg
	Levothyroxine	S,T	Tablets	0.1mg
	Iodine	S,T	Solution	8 mg, 5ml
19.	**Immunologicals**			
19.1	Diagnostic Agents			
	Tuberculin, Purified Protein Derivative	U	Injection	
19.2	Sera and Immunoglobulins			
	Anti-D Immunoglobulin (Human)	S,T	Injection	250mg, 300mg
	Antisnake Venom	U	Injection	10 ml

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Antitetanus Human Immunoglobin	U	Injection	250 IU, 500 IU
	Diphtheria Antitoxin	S,T	Injection	10,000 IU
	Rabies Immunoglobulin	U	Injection	150 IU/ml
19.3	Vaccines			
19.3.1	For Universal Immunization			
	B.C.G Vaccine	U	Injection	
	D.P.T Vaccine	U	Injection	
	Hepatitis B Vaccine	U	Injection	
	Measles Vaccine	U	Injection	
	Oral Poliomyelitis Vaccine (Live Attenuated)	U	Injection	
19.3.2	For Specific Group of Individuals			
	Rabies Vaccine	U	Injection	
	Tetanus Toxoid	U	Injection	
20.	**Muscle Relaxants (peripherally acting) and Cholinesterase inhibitors**			
21.	**Ophthalmological Preparations**			
21.1	Antiinfective Agents			
	Chloramphenicol	U	Drops/ointment	0.4%. 1%
	Ciprofloxacin Hydrochloride	U	Drops/ointment	0.3%
	Gentamicin	U	Drops	0.3%
	Miconazole	U	Drops	1%
	Povidone Iodine	S,T	Drops	0.6%
	Sulphacetamide Sodium	U	Drops	10%, 20%, 30%

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Tetracycline Hydrochloride	U	Ointment	1%
21.2	Antiinflammatory Agents			
	Prednisolone Acetate	U	Drops	0.1%
	Prednisolone Sodium Phosphate	U	Drops	1%
	Xylometazoline	U	Drops	0.05%, 0.1%
21.3	Local Anaesthetics			
	Tetracaine Hydrochloride	U	Drops	0.5%
21.4	Miotics and Antiglaucoma Medicines			
	Acetazolamide	S,T	Tablets	250 mg
	Betaxolol Hydrochloride	S,T	Drops	0.25%, 0.5%
	Physostigmine Salicylate*	S,T	Drops	0.25%
	Pilocarpine	S,T	Drops	2%, 4%
	Timolol Maleate	S,T	Drops	0.25%, 0.5%
21.5	Mydriatics			
	Atropine Sulphate	U	Drops/ointment	1%
	Homatropine	U	Drops	2%
	Phenylephrine	U	Drops	5%
21.6	Ophthalmic Surgical Aids			
	Methyl Cellulose*	T	Injection	2%

*Complementary

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
22.	**Oxytocics and Antioxytocics**			
22.1	Oxytocics			
	Methyl Ergometrine	U	Tablets Injection	0.125 mg 0.2 mg/ml
	Mifepristone	T	Tablets	200 mg
	Oxytocin	S,T	Injection	5 IU/ml 10 IU/ml
22.2	Antioxytocics			
	Isoxsuprine Hydrochloride	S,T	Tablets Injection	10mg 5 mg/ml
	Terbutaline Sulphate	S,T	Tablets Injection	2.5 mg 0.5 mg
23.	**Peritoneal Dialysis Solution**			
Intraperitoneal Dialysis Solution (of approximate composition)				
24.	**Psychotherapeutic Medicines**			
24.1	Medicines used in Psychotic Disorders			
	Chlorpromazine Hydrochloride	U	Tablets Syrup Injection	25 mg 50 mg 100 mg 25 mg/5 ml 25 mg/ml
	Haloperidol	S,T	Tablets	1.5mg, 5mg 10 mg 5 mg/ml
	Trifluoperazine	S,T	Tablets	5mg, 10mg
24.2	Medicines used in Mood Disorders			
24.2.1	Medicines used in Depressive Disorders			
	Amitriptyline	U	Tablets	25 mg

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
	Fluoxetine Hydrochloride	U	Capsules	20mg
	Imipramine	U	Tablets	25mg, 75 mg
24.2.2	Medicines used in Bipolar Disorders			
	Lithium Carbonate	T	Tablets	150 mg
24.3	Medicines used for Generalized Anxiety and Sleep Disorders			
	Alprazolam	U	Tablets	0.25mg, 0.5 mg
	Diazepam	U	Tablets	2 mg, 5 mg, 10 mg
	Nitrazepam	U	Tablets	5 mg, 10 mg
24.4	Medicines used for Obsessive Compulsive Disorders and Panic Attacks			
	Clomipramine Hydrochloride	S,T	Tablets	10 mg, 25 mg
25.	**Medicines Acting on the Respiratory Tract**			
25.1	Antiasthmatic Medicines			
	Aminophylline	U	Injection	25 mg/ml
	Beclomethasone Dipropionate	U	Inhalation	50 mg, 250 mg/dose
	Hydrocortisone Sodium Succinate	U	Tablets	100 mg 200 mg 100 mg/dose
	Salbutamol Sulphate	U	Tablets	2 mg, 4 mg
	Theophylline Compounds	U	Tablets	100 mg, 200 mg

	Medicine	Category	Route of Administration/ Dosage Form	Strengths
25.2	Antitussives			
	Codeine Phosphate	U	Tablets Syrup	10 mg 15 mg/ 5ml
	Dextromethorphan	U	Tablets	30 mg
26.	**Solutions correcting Water, Electrolyte and Acid-Base Disturbances**			
26.1	Oral			
	Oral Rehydration Salts	U	Powder for solution	As per IP
26.2	Parenteral			
	Glucose	U	Injection	5% isotonic 50% hypertonic
	Glucose with Sodium Chloride	U	Injection	5%+0.9%
	Normal Saline	U	Injection	0.9%
	N/2 Saline	S,T	Injection	
	N/5 Saline	S,T	Injection	
	Potassium Chloride	U	Injection	11.2% Sol.
	Ringer Lactate	U	Injection	
	Sodium Bicarbonate	U	Injection	
26.3	Miscellaneous			
	Water for Injection	U	Injection	2ml, 5 ml 10 ml
27.	**Vitamin and Minerals**			
	Ascorbic Acid	U	Tablets	100 mg,500 mg
	Calcium Salts	U	Tablets	250 mg, 500mg
	Multivitamins (as per Schedule)	U	Tablets	

Medicine	Category	Route of Administration/ Dosage Form	Strengths
Nicotinamide	U	Tablets	50 mg
Pyridoxine	U	Tablets	25 mg
Riboflavine	U	Tablets	5 mg
Thiamine	U	Tablets	100 mg
Vitamin A	U	Tablets Capsules Injection	5000 IU 10,000 IU 50,000 IU 50,000 IU/ml
Vitamin D_3 (Ergocalciferol)	S,T	Capsules	0.25mg, 1 mg

Source: Ministry of Health and Family Welfare, Government of India, 2003.

CENTRAL DRUGS CONTROL ADMINISTRATION

(a) Central Authorities

Under the Drug and Cosmetics Act, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control 0rganisations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Drug Controller General of India is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I.V. Fluids, Vaccine and Sera.

Central Drugs Standard Control Organization is located at Nirman Bhawan, New Delhi 110011 and functions under the Directorate General of Health Services.

Its senior officers include:

Drugs Controller General of India
Ashwini Kumar, Drug Controller General of India (I/c)
Phones: (Off.) 3018806, Fax: 91-11-23012648 (Resi.) 6252215 / 6252678.
Email: dcgi@cdsco.nic.in

Deputy Drugs Controllers
A.B. Ramteke, Phone: 3017329
S.P. Das, Phone: 3017212
B.R. Wadhavan, Phone: 3017329
R. Narayanaswamy, Phone: 3017212
S.D.Vijaya Raghavan, Asstt. Drugs Controller (India). Phone: 3017212

Technical Officers
A.K. Pradhan, Phone: 3022200/2668.
Lalit Kishore, Phone: 3022200/2668.
Janak Raj, Phone: 3022200/2668.
B.K. Bandyopadhyay, Phone: 3018806.
Ms. Manjula Chandra, Phone: 3022200/2767.
S.P. Shani, Phone: 3022200/2767.

ZONAL OFFICES OF CENTRAL DRUGS STANDARD CONTROL ORGANISATION (CDSCO)

The Central Government have established four zonal offices of the Central Drug Standard Control Organisation at Mumbai, Kolkata, Chennai, and Ghaziabad. The Zonal Offices work in close collaboration with the State Drug Control Administration and assist them in securing uniform

enforcement of the Drug Act and other connected legislation's, on all India basis. The names of the office-in-charge of the Zonal Organisations, their address and names of the States are as follows:

EAST ZONE

Andaman and Nicobar Island, Arunachal Pradesh, Assam, Bihar, Manipur, Meghalaya, Mizoram, Nagaland, Orissa, Sikkim, Tripura & West Bengal.

G.N. Ray, I/C, Deputy Drug Controller, India, Central Drug Standard Control Organisation, East Zone, C.G.O. Bldgs., (Nizam Palace) West, 2nd Floor, 234/4, Lower Circular Road, Kolkata – 700 020. Phone: Offi.: 2470513, Gram: ZONDRUG-KOLKATA. Fax: 2813806.

Drug Inspectors
Sankar Gupta
Debashish Ray
S. Mukhopadhyay
B.K. Samantaray
Surajit Tamuli
Smt. Rubina Bose
Sub-Zonal Office:

Asstt. Drug Controller (India), Salimpur Ahra, Behind R.B.I., Patna - 800 003. Phone: 666714.

WEST ZONE

Chattisgarh, Goa, Daman & Diu, Gujarat, Madhya Pradesh and Maharashtra.

M.Venkateswarlu, Deputy Drugs Controller (India), Central Drug Standards Control Organisation, West Zone, C.G.H.S. Dispensary No. 8, First Floor, Kane Nagar, Antop Hill, Mumbai – 400 037. Phones: 91-22-4026353, 4011091. Gram: ZONDRUG-MATUNGA, MUMBAI. Fax: 91 (22) 4015125.

Drug Inspectors
K. Bhargava
S.E. Reddy
A. Ramakishan
V.G. Somani

Subzonal Office (Ahmedabad)
Drug Inspector
A Ram Krishan

NORTH ZONE

Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Rajasthan, Uttaranchal, Uttar Pradesh, N.C.T. of Delhi & Union Territory of Chandigarh.

Dr. S.R. Gupta, M.Sc., Ph.D., Joint Drug Controller, India, Central Drug Standard Control Organisation, North Zone, C.G.O. Building-I, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad – 201 002 (U.P.). Phones/Fax: Offi.: 91-4719483, 4750013, Resi.: 2222280, Gram: ZONDRUG-GHAZIABAD.

Asstt. Drugs Controller (India)
P.K. Rastogi

Drug Inspectors
Dr. D. Roy, Ph.D., F.I.C.
M. Mitra, B. Pharm
Dinesh Kumar Chauhan, B. Pharm
Gulshan Taneja, B.Pharm, P.G.D.M.S.
Arvind Kukrety
Sanjeev Kumar

SOUTH ZONE

Andhra Pradesh, Karnataka, Kerala, Pondicherry and Tamil Nadu.

A.R. Singh, Deputy Drug Controller, India, Central Drug Standard Control Organisation, South Zone, 2nd Floor, Shastri Bhawan, Annexe, 26, Haddows Road, Chennai – 600 006. Phone: Off. 8278186. Gram: ZONEDRUG-CHENNAI. Telefax: 044-8213079.

Drug Inspectors

A. Krishna Dev, B. Pharm
Smt. Shanthy Gunasekharan, M. Pharm
P.B.N. Prasad, M. Pharm
S. Mannivannan, B. Pharm
B. Kumar, B. Pharm
A. Senkathir, B. Pharm

Sub-Zonal, Hyderabad

D.P. Sharma, Asstt. Drug Controller (India), CDSCO, Sub-Zonal, Air Cargo Complex, 1-10-1 to 8, Sardar Patel Road, Begumpet, Hyderabad – 500 016. Phone: 7760141.

Drug Inspectors

G. Nageswara Rao, M. Pharm, DBM (DIP)
A. Chandra Sekar Rao, M. Pharm

ASSISTANT DRUGS CONTROLLERS AT PORTS

CHENNAI

C. Samuel Deva Prasad, Asstt. Drugs Controller (India) – Port, Room No. 23, IV Floor, Annexe Bldg., Custom House, Chennai – 600 001. Phone: Offi: 5212041. Gram: DRUGCONIND.

A.N. Shanmugam, Technical Officer, Office of the Asstt. Drug Controller (India) – Port, IV Floor, Annexe Bldg., Customs House, Chennai – 600 001. Phone: 5212041.

R. Arivudai Nambi, Technical Officer, Central Drug Standard Control Organisation, Air Cargo Complex, Meenambakkam Air Port, Chennai – 600 027. Phone: 2343698.

COCHIN

Technical Officer, Central Drug Standard Control Organisation, Ministry of Health & Family Welfare, Custom House, Cochin – 682 009 (Kerala). Phone: 0484-666042. Gram: DRUGCONIND.

DELHI

H.G. Gujral, Asstt. Drugs Controller (India), Customs House, Indira Gandhi International Airport, New Delhi.

KOLKATA

G.N. Ray, Asstt. Drug Controller, India, Customs House, 15/1, Strand Road, Kolkata – 700 001. Phones: Offi.: 2436867. Resi.: 4300376. Gram: DRUGCONIND.

Technical Officer, Air Cargo Complex, N.S.C. Bose International Airport, Kolkata-700 052. Phone: 5119851.

MUMBAI

A.K. Sinha, Asstt. Drug Controller, India, 6th Floor, Annexe Bldg., New Custom House, Ballard Estate, Fort, Mumbai – 400 038. Phones: Offi.: 2611596. Resi.: 5410382. Gram: DRUGCONIND. Fax: 2634550.

L.H. Tandel, Technical Officer, CDSCO, 6th Floor, Annexe Bldg., New Custom House, Ballard Estate, Fort, Mumbai – 400 038. Phone: Offi.: 2611596, Gram: DRUGCONIND. Fax: 2634550.

Technical Officer, CDSCO, 6th Floor, Annex Bldg., New Customs House, Ballard Estate, Fort, Mumbai – 400 038. Phone: 2611596. Gram: DRUGCONIND. Fax: 2634550.

Mrs. S.D. Wadiwala, Technical Officer (Air Port), Central Drug Standard Control Organisation, International Air Cargo Complex, Sahar Village, Andheri, Mumbai – 400 099. Phone: 8320152.

Jawaharlal Nehru Port (Nhava Sheva)

A.K. Sinha, Assistant Drugs Controller (India), JNPT CFS (Imports), Nhava Sheva, Navi Mumbai – 400 707. Phones: (Offi.): 7242698, (Resi.): 5410382, Fax: 7240139.
Drug Inspector's Training Scheme (DITS)

Vishwa Vibhuti, Incharge, Drugs Inspectors' Training Scheme, C.G.H.S. Dispensary Bldg., First Floor, C.G.S. Colony, Kane Nagar, Antop Hill, Mumbai – 400 037. Phones: Offi.: 4011091, 4015125. Fax: 4015125.

Central Drugs Laboratory (CDL)

The Central Drugs Laboratory, Kolkata is the national statutory laboratory of the Government of India for quality control of Drug and Cosmetics and is established under the Indian Drug & Cosmetics Act, 1940. It is the oldest quality control laboratory of the Drug Control Authorities in India. If functions under the administrative control of the Director-General of Health Services in the Ministry of Health and Family Welfare.
The functions of the Laboratory include:

I. Statutory Functions:

a. Analytical quality control of majority of the imported Drug available in Indian market.
b. Analytical quality control of drug and cosmetics manufactured within the country on behalf of the Central and State Drug Controller Administrations.
c. Acting as an Appellate authority in matters of disputes relating to quality of Drug.

II. Other Functions:

d. Collection, storage and distribution of International Standard International Reference Preparations of Drug and Pharmaceutical Substances.
e. Preparation of National Reference Standards and maintenance of such Standards. Maintenance of microbial cultures useful in drug analysis Distribution of Standards and cultures to State Quality Control Laboratories and drug manufacturing establishments.
f. Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions.
g. Training of World Health Organisation Fellows from abroad on modern methods of Drug Analysis.
h. To advise the Central Drug Control Administration in respect of quality and toxicity of drug awaiting licence.
i. To work out analytical specifications for preparation of Monographs for the Indian Pharmacopoeia and the Homeopathic Pharmacopoeia of India.
j. To undertake analytical research on

standardisation and methodology of Drug and cosmetics.

k. Analysis of Cosmetics received as survey samples from Central Drug Standard Control Organisation.

l. Quick analysis of life saving Drug on an All-India basis received under National Survey of Quality of Essential Drug Programme from Zonal Offices of Central Drug Standard Control Organisation.

In addition to the above functions the Central Drug Laboratory also actively collaborates with the World Health Organisation in the preparation of International Standards and Specifications for International Pharmacopoeia. It also undertakes collaborative study on behalf of the Indian Pharmacopoeia Committee. The senior Officers of the Laboratory have been appointed as Government Analysts on behalf of most of the States of the Union for analysis of drug samples.

The Director of CDL is B. Mandal, M.Sc., Director, Central Drugs Laboratory, 3, Kyd Street, Kolkata – 700 016. Phone: 2299541, Gram: BIOSTANLAB. Fax: 033-2299380.

CENTRAL DRUGS TESTING LABORATORY (CDTL) CHENNAI

Central Drug Testing Laboratory is one of the four National Laboratories in India engaged in the research and analysis of Drug and Cosmetics as per Drug and Cosmetics Act, 1940.

The Director of the CDTL Chennai is, A.R. Singh, Dy. Drug Controller (India), Director (Acting), Central Drug Testing Laboratory, Govt. of India, 37, Naval Hospital Road, Periamet, Campus G.M.S.D., Chennai – 600 073. Phone: 5386402, Fax: 044-5386402.

CENTRAL DRUGS TESTING LABORATORY (CDTL) MUMBAI

The Central Drugs Testing Laboratory – Mumbai is another national statutory laboratory of the Government of India, functioning under administrative control of the Drug Controller General (India), DGHS, Ministry of Health and Family Welfare.

The major functions of the laboratory include:

Testing of imported bulk drugs and formulations referred by ADCs, Mumbai, Nhava Sheva & Chennai, Survey and Watchers samples referred by Deputy Drugs Controller (India), West Zone. Lately, new drugs and formulations are also being referred by the Drugs Controller General (India). The laboratory is notified as Appellate Laboratory for Copper T Intra-Uterine Contraceptive Device and Tubal Rings under the Drugs and Cosmetics Rules, (Medical Stores) & Regional Directors of Department of Family Welfare and procurement and field samples of Oral Contraceptive Pills, Copper T and Tubal Rings referred by the Dept. of Family Welfare.

The Director of the Laboratory is Dr. K.V. Jogi. M.Pharm, Ph.D, Central Drugs Testing Laboratory-Mumbai, 4th Floor, ESIS Hospital Bldg., Road No. 33, Wagle Estate. Thane-400 604 (Maharashtra). Phones: Offi.: 5823843,

5825057, (Resi.): 5829774, Gram: DRUGSLAB, Telefax: 5832575.

mailto: parthajg@sify.com
mailto: pig.rdtl@assam.nic.in

Central Drugs Testing Laboratory (CDTL) Guwahati

"The Regional Drugs Testing Laboratory Guwahati is the one of the five National Laboratory of the Govt. of India for quality control of Drugs and Cosmetic and is established under the Indian Drugs & Cosmetics Act 1940 functioning under administrative control of the Drugs Controller General of India and sub ordinate office under Directorate General of Health Services, Ministry of Health & Family Welfare. The laboratory was set up in the year 2002 for entire North Eastern State including Sikkim and is housed in its own building at Guwahati.

1. Statutory Function

a. Analytical quality control of drugs and cosmetic manufactured within the country on behalf of the Central and State Drugs Controller Administration.
b. To assists the Central Drugs Standard Control Organization in the testing of Drugs and cosmetic.

The laboratory is headed by :
Mr. Parthajyoti Gogoi,
M.Pharm (Tech),
Government Analyst,
Officer-in-Charge Regional Drugs Testing Laboratory,
Guwahati-781 037 (Assam)
Phones-Off-0361-2338555/2330555(Tele-Fax) ,
Resi.: 0361-2337272/233899
e-mail: parthajyoti@sancharnet.in

Central Indian Pharmacopoeia Laboratory (CIPL)

Central Indian Pharmacopoeia Laboratory is the national statutory laboratory of Government of India for quality control of Drugs and Cosmetics and is established under the Indian Drugs and Cosmetics Act, 1940. It functions under the administrative control of Director General of Health Services in the Ministry of Health and Family Welfare. Its functions are:

m. To draw up standards and analytical specifications for monographs to be incorporated in the Indian Pharmacopoeia.
n. To function as government Analyst for such states who do not have their own testing facilities.
o. To assist the central Drug Standard Control Organization in the testing of drugs and cosmetics.
p. To carry out the work pertaining to the National Formulary of India.
q. Quality control of mechanical contraceptives under Drugs and Cosmetics Act.
r. To act as appellate authority in matters of dispute relating to quality of condoms.
s. To carry out investigations for establishing simpler and reliable methods of analyzing drugs and their preparations.
t. To carry out research work for standardizing and characterizing

drugs incorporated in the Indian Pharmacopoeia.

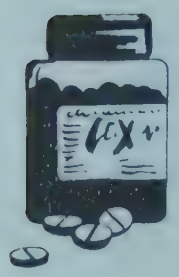
u. Training of Drug Analysts of Drug Control Laboratories of different states.

v. Nodal centre for regular condom testing, research & training for other Condom Testing Laboratories.

In addition to above functions, the laboratory actively collaborates with World Health Organisation in preparation of standards and specifications for international Pharmacopoeia. It also undertakes collaborative studies on behalf of Indian Pharmacopoeia Committee. The laboratory is approved as research Centre by Meerut University. The laboratory is housed in its own building.

The laboratory is headed by Dr. G.N. Singh, Director, Central Indian Pharmacopoeia Laboratory, Raj Nagar, Sector-23, Ghaziabad, 201002 (U.P.). Phones: Off. 91-4783400, 91-4783392, 91-4783401 (Direct), Gram: CIPLAB, Fax: 091-4783311, e-mail: goicipl@nda.vsnl.net.in

Source: www.cdsco.nic.in/htm/Central.htm
(Website of Central Drugs Standards and Control Organization)



FURTHER INFORMATION DRUG EDUCATION INFORMATION MATERIAL PAST & PRESENT

Material prepared by VHAI, AIDAN & other groups as part of efforts and campaign for Rational Drug Use and Rational Drug Policy over the years – produced here as part of process documentation an effort in compiling, updating of drug information from various sources for sharing and facilitating reading for understanding and appropriate health action for Rational Drug Use has been made.

THE INDIAN DRUG SCENE			
1.	The Drug Situation in India	1982, Dr. Mira Shiva	VHAI
2.	A Study of Prevalent Diseases in India and Production of Some Essential Drugs	1982, J.S. Mazumdar	FMRAI
3.	Community Health Needs and India's Drug Industry	1984	JNU
4.	Drugs As if People Mattered: Special Edition of Health for the Millions	1981 (April/June) Dr. Mira Shiva	VHAI
5.	People Vs Profits: Health for the Millions	1986	VHAI
HAZARDOUS DRUGS			
1.	Hazardous, banned, bannable and dumped Drugs	1984, Dr. Mira Shiva	VHAI
2.	The Clioquinol Controversy	1982, Dr.Mira Shiva	VHAI

3.	Anti-diarrhoeals: Focus on Clioquinol	1983,	Dr. Mira Shiva	VHAI
4.	Why amidopyrines (including analgin) must go	1982,	"	VHAI
5.	Some painful facts about a painkiller called amidopyrine	1983,	"	VHAI
6.	Using tetracycline for children and pregnant women	1982,	"	VHAI
7.	Anabolic steroids	1982,	"	VHAI
8.	Why not to prescribe anabolic steroids	1982,	"	VHAI
9.	Oxyphenbutaone-Phenylbutazone	1984,	"	VHAI
10.	Fixed-dose Combinations of Steroids	1984,	"	VHAI
11.	Misuse of antibiotics	1984,	"	VHAI
12.	Selection of appropriate analgesic and-inflammatory drugs	1984,	"	VHAI
13.	Hormonal Pregnancy Tests (E.P. Drugs)	1982,	Dr. C. Sathyamala	MFC
	a. Are hormonal pregnancy tests safe?	1982,	"	MFC
	b. Dear Sister letter for the EP Campaign	1982	Dr. Mira Shiva	VHAI
	c. References on Oestrogen-Progesterone test for Pregnancy	1982	"	VHAI
	d. Dear Doctor/Chemist letter	1982	"	VHAI
	e. Review of supportive hormone therapy in Obstetrics	1982	"	VHAI

	f. Oestrogen-Progesterone drug campaign	1982, Dr. Mira Shiva	VHAI
	g. A letter seeking immediate ban on high dose Estrogen-Progesterone combination drugs	1982 "	VHAI
	h. Warning poster against hormonal Pregnancy tests	1982 "	VHAI & SAHELI
	i. The case against EP Forte – a review of the controversy	1982 "	VHAI
	j. E.P. Update	1983 "	VHAI
	k. The unfinished EP Campaign	1984 "	VHAI
	l. The EP information Pack Facts	1986, Dr. Mira Shiva, Radha Holla Bhar	GROWTH INITIATIVE
14.	Hazardous Drugs Booklet	1989	MFC & AIDAN
15.	Depo Provera	Dr. C. Sathyamala	MFC
16.	Net En submission	Dr. C. Sathyamala	MFC, Saheli
17.	Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India	2004	LOCOST
18.	Surviving the Pharmaceutical Jungle	2004, Dr. Nabojeet Roy	Forum for Medical Ethics
19.	Drug Supply and Use: towards `` a rational policy in India	1998, Dr. Anant Phadke	Sage Publications New Delhi

IRRATIONAL DRUGS

1.	Scientific scrutiny of some over-the-counter drugs	1982, Dr. Anant Phadke	MFC
2.	Misuse of antibiotics	1984, Dr. Anant Phadke	MFC

3.	Fixed-dose combinations of steriods	1984	AIDAN
4.	Anti-diarrhoeal formulations : a rationality study	1985, Dr. Anant Phadke	MFC
5.	A Rationality Study of Analgesics and Anti-Pyretics	1985, Dr. Anant Phadke	MFC
6.	Tonics – How much of an economic waste	1994, Dr. Kamla Jairao	VHAI
7.	ORT	1979, Dr. Anant Phadke	MFC
ESSENTIAL DRUGS			
1.	Essential Drugs – demand for prioritization	1984, Dr. Mira Shiva	VHAI
2.	Graded Essential Drug List	1984, Dr. Mira Shiva	VHAI
3.	A study of prevalent diseases in India and production of some essential drugs	1982, J.S. Mazumdar	FMRAI
4.	WHO's list of essential drugs (Reprint of T.R.S. 722)	1986	VHAI
5.	Hathi Committee's List of Essential Drugs, Reprint	1982	VHAI
6.	Lists of Essential Drugs – A Comparison	1983, Dr. Mira Shiva	VHAI
7.	Essential Drugs Lists	1996	LOCOST
8.	The selection and use of essential medicine report of the WHO Expert Committee	2003	WHO
9.	How to develop and implement a	1995	Deptt. of

	national drug policy : agenda to good prescribing a practical manual medicine		Essential drugs & policy - WHO
10.	Access to Essential Drugs	2002, Amitava Guha	FMRAI 372/21 East Pusa Rd. Kolkata 700 033
RATIONAL DRUG THERAPY			
1.	What is rational drug therapy?	1982, Dr.Mira Shiva	VHAI
2.	Rational Therapeutics	1983	MFC
3.	Selection of appropriate analgesic and anti-inflammatory drugs	1984, Dr. Anant Phadke	MFC
5.	Rational Selection of Drugs – International Consultation Report	1986, Dr. Mira Shiva	VHAI
6.	What is Rational Drug Therapy?	1987, Dr. Mira Shiva	VHAI
7.	Rational Drug Therapy	1988	Junior Doctors Forum Calicut Medical College
8.	Rational Use of Medicines	1994, Dr. Mira Shiva	VHAI
9.	Rational Drug Use	1995	VHAI, FEDCOT
RATIONAL DIARRHOEA CARE			
1.	Causes of Diarrhoea	1983, Dr. Mira Shiva	VHAI

2.	Diarrhoea and significance of the problem	1983	VHAI
3.	Diarrhoea and malnutrition	1983, Dr. Mira Shiva	VHAI
4.	Management of acute diarrhoea	1983	VHAI
5.	Low cost drugs managing diarrhoea	1983, Dr. Mira Shiva	VHAI
6.	Drugs in the treatment of diarrhoea	1983	VHAI
7.	Cost effectiveness of the different options available and situations in which they may be appropriate	1983, Dr. Mira Shiva	VHAI
8.	Anti-diarrhoeals – their misuse. Focus on clioquinols e.g. Mexaform, Enterovioform and their side effects, SMON	1983	VHAI
9.	VHAI's role in diarrhoea care	1983, Dr. Mira Shiva	VHAI
10.	Special issue of Health for the Millions on Diarrhoea	1983	VHAI
11.	Anti-diarrhoeal formulations – a rationality study	1984, Dr. Anant Phadke	MFC
12.	Taste of Tears Better care in Diarrhoea	1984 Dr. Mira Shiva Dr. Aspi Mistry	VHAI
13.	Problem Packets Commercial ORS packets	1994	VHAI
14.	Diseases & Conditions with Epidemic Potential	2000 Dr. Bir Singh	VHAI
RATIONAL TUBERCULOSIS CARE			
1.	Seeking information regarding anti-TB drugshortages	1982, Dr. Mira Shiva	VHAI

2.	Rational TB Care – A priority	1983, Dr. Mira Shiva	VHAI
3.	VHAI's role in TB Care	1984, Dr. Mira Shiva	VHAI
4.	The BCG story	1984	VHAI
5.	CMC Ludhiana – An experience in TB care	1984, Dr. Mira Shiva	VHAI
6.	TB care – A Continuing Commitment	1983, Dr. Mira Shiva	VHAI
7.	Drug production for a National Priority Programme – TB	1985	VHAI
8.	National Consultation on TB	1994 Dr Anil	VHAI
AMNIOCENTESIS – for sex determination			
1.	A world without women – sex determination tests	1983	SAHELI
2.	Scarcer half	1984, Vimala Balsubramanium	CED
3.	Submission to the Parliamentary Committee	1991	VHAI, Saheli, Action India etc.
4.	Darkness at Noon	2003, Dr. Ashish Bose Dr. Mira Shiva	VHAI
BANNING DRUGS AND DRUG LAW			
1.	Banning of Drugs	1982, Dr. Mira Shiva	VHAI
2.	Some instances of drug dumping	1982, Dr. Mira Shiva	VHAI
3.	Drugs and Magic Remedies Act	1984	CERC
4.	Drugs and Cosmetics Act – Updating necessary Pharmacy Act	1983	VHAI

5.	Pharmacy Act Amendment	1983	VHAI
6.	A note on the legal aspects of health issues and VHAI's intervention	1983, Dr. Mira Shiva	VHAI
RATIONAL DRUG POLICY			
1.	People Oriented Drug Policy – Mozambique	1983	VHAI
2.	Memorandum: Demand for A Rational Drug Policy for India	1983	VHAI
3.	Memorandum for a National Drug Policy	1983	AIDAN
4.	Towards an Alternative Drug Policy – some criteria	1984	FMRAI
5.	Criteria of Rational Drug Policy	1984	DAF WB
6.	AIDAN Working Group Response to Steering Committee Recommendations	1984	AIDAN
7.	Drug Pricing & Pricing Policy	1984	ADM
8.	AIDAN's Rational Drug Policy Statement	1985	AIDAN
9.	Rational Drug Policy Kit	1986	VHAI
10.	Rational Drug Policy (Problems and Recommendations)	1986	AIDAN
11.	Drugs as if people mattered, Medical Service	1986	CHAI
12.	Critique of the National Health Policy	1987	VHAI
13.	Critique of the New Drug Policy	1986	VHAI

14.	Drug Industry and the Indian People	1985	DSF & FMRAI
15.	National Drug Policy – Submission to the Parliament	1994	VHAI, AIDAN, NCCDP
16.	Critique of Drug Policy	1994	VHAI
17.	Medicines Medical Care & Drug Policy	2000, Dr. Mira Shiva	VHAI/ICHI

RATIONAL DRUG ECONOMY

1.	General administration of the Pharmacy	1984	CMAI
2.	Medicines Procurement and Stock ControlPurchase of Medicines	1984	CMAI
3.	Central Drug Marketing Unit – Initiative in Bulk Purchase	1983	WBVHA
4.	Tablet Mission Industry Bangarpet	1982	VHAI
5.	Prescriber's Guide	1987	CDMU (WB)
6.	A Decade after Hathi Committee	1988	KSSP
7.	Medicines Medical Practice & Health Care in India in the Era of Globalisation, Political Economy Perspectives	2004, Dr Amit Ray	ICDHI

CODES OF PRACTICE FOR DRUG MARKETING

1.	10 Commandments of the drug companies	1982 Augustien Veliath	VHAI
2.	Antidotes to the drug industry Code & You	1982 Dr. Mira Shiva	VHAI

3.	What consumers can do	1983 Dr. Mira Shiva	VHAI
4.	Drug information for consumer		Consumer Concerns
5.	Inadequate information on OTC Analgesic Drugs	1983	CERC
LEGAL ACTION			
1.	In the Supreme Court of India – Civil Writ Petition No. 3492 of 1983, Under Article 32 of the Constitution of India	1983, Dr Vincent Pallikulangara	PLC
2.	Amendment of the above public writ petition		PLC
3.	Net-en submission (long acting injectableContraceptive)		SAHELI
4.	Submission for the public hearing on High Dose EP drugs	1987	SAHELI VHAI, AIDAN & ACASH
5.	Petition on EP drugs	1988	ACASH
6.	Submissions Supreme Court – Hazardous Drugs: Writ Petition No. (C) No. 698 of 1993	1993	DAFK, AIDAN, NCCDP, LOCOST, CDMU & SAHELI
7.	Supreme Court PIL on Q uina Crine Trials		JNU, AIDWA
8.	SLP (Special Leave Petition 3668 of 2003 on Essential Drugs & Drug Pricing in the matter of Union of India vs K.S. Gopinath		AIDAN, MFC, Locost,

			JSS & others
BANGLADESH DRUG POLICY			
1.	In support of Bangladesh's Drug Policy	1982	VHA
2.	Drug Control Ordinance Promulgated	1982	VHAI
3.	The Bangladesh ban on hazardous and irrational drugs, its review andpresent status	1982	VHAI
4.	National Drug Policy for Bangladesh, from Expert Committee Report	1982	VHAI
5.	Bangladesh War – Part I and Part II	1982	VHAI
6.	Bangladesh – Finding the right prescription (special edition of Health for Millions)	1982	VHAI
7.	Essential Drugs for the Poor – a myth a reality	1982	GK
8.	Gonoshasthya Kendra – People's Health Centre	1983	VHAI
9.	A courageous Drug Policy – The Bangladesh example	1986	VHAI
10.	Bangladesh Drug Policy – 4 years on	1987	IOCU
11.	Bangladesh Drug Policy	1993	IOCU
12.	The politics of Essential Drugs	1996, Dr. Zafrullah Chowdhury	ZED Press/Vistaar Press
CONSUMER ALERTS			
1.	Clioquinol – withdrawal of Mexaform	1984	VHAI
2.	Oxyphenbutazone and Phenylbutazone - withdrawal of Tanderil	1984	VHAI

3.	U.S. Bill to allow exports of hazardous drugs	1984	VHAI
4.	Re-entry of Hatch Bill (U.S.A.) to allow export of hazardous drugs	1985	VHAI
5.	U.N. consolidated list – exclusion of brand names	1985	VHAI
6.	J.J. Deaths	1988	VHAI
RATIONAL DRUG CAMPAIGNERS			
1.	Dr Olle Hansson		VHAI
2.	Dr Olle Hansson – The Passing away of a health campaigner	1985	VHAI
3.	Dr Andrew Herxheimer	1985	VHAI
4.	Dr Zafarullah Chowdhury	1982	VHAI
VHAI AND THE DRUGS ISSUE			
1.	Our concern about drugs	1982	VHAI
2.	The Voluntary Health Association of India - its activities and its role in Low Cost Drugs	1983	VHAI
Note: Most of the above have been prepared as cyclostyled handouts to keep costs low and for increased distribution for peoples education and health action. The principles of Rational Drug Use are still relevant and the struggles towards it ongoing.			
DRUGS IN INDIA			
1.	Hathi Committee Report	1975	Government of India,
2.	Aspects of the Drug industry in India	1982	Mukarram Bhagat, CED Mumbai

3.	Health for all: An Alternative Strategy	1981	ICSSR &ICMR Joint Committee Report
4.	The Indian Pharmaceutical Industry: Problem and prospects	1984	P.L. Narayan (NCAER)
5.	Statement of National Health Policy	1983	Govt. of India
6.	Multi-Nationals and the Pharmaceutical Industry in India	1985	KSSP
7.	Drugs for the people or people for the drugs (Bengali & Hindi)	1985	DAF WB
8.	List of Banned Drugs (Bengali)	1985	DAF WB
9.	Drug industry & the Indian People	1985	DSF & FMRAI
10.	Issues in the Drug Policy Group	1987	Pondicherry Science Forum
11.	A Decade After Hathi Committee	1988	KSSP
12.	CDMU Drug information	1988	CDMU
13.	Rational Drug Use in Medical Education	1992	ERDU
14.	Delhi State Drug Formulary	2001	DSPRUD
15.	Standard Treatment Guidelines	2001	DSPRUD
16.	Delhi State Essential Drug Policy	2001	DSPRUD
ON INTERNATIONAL CODES			
	International Federation of Pharmaceutical Manufacturers Association - Code	1982	IFPMA
	International Codes and You	1984	VHAI

Ethical Criteria for Marketing of Pharmaceuticals				WHO
NATIONAL LEGISLATION				
Drugs and Cosmetics Act			1940	
Drugs and Cosmetics Amendment Act			1982	
Consumer Protection Act			1986	
ON HEALTH AND DRUGS				
1.	In Search of Diagnosis		1977	MFC
2.	Under the Lens		1986	MFC
3.	Where There is No Doctor	David Werner	1980, 1988, 1994	VHAI
4.	Private Sector Privatisation in the Health Sector	Ravi Duggal	1993	FRCH
5.	Rakku's Story	Shiela Zurbigg	1988	Centre for Social Action
6.	Health Situation in India	Dr. N.H. Antia	1990	FRCH
7.	State of India's Health		1992	VHAI
8.	People's Health in People's Hand	Dr. N.H. Antia	1993	FRCH
9.	Independent Commission on Health in India		1996	ICHI
10.	Health Situation in India	Dr N.S. Deodhar	2001	ICHI
11.	Regulating Medicine Ethics	R. Srinivasan	2000	VHAI/ICHI
12.	The Private Health Sector in India - Nature, Trends & a Crititique	Ravi Duggal	2000	VHAI
13.	Medical Ethics for Self Regulation of Medical Profession and Practice	Aditi Iyer Amar Jesani	2000	VHAI/ICHI

14.	Anubhav - Malaria	Dr. P.N. Sehgal	1996	VHAI
15.	Anubhav - Tuberculosis	Dr. P. Siddhu Phadke	1996	VHAI
16.	Towards an Appropriate Malaria Control Strategy (Issues of concerns & alternatives for action)		1997	VHAI & SOCHARA
17.	Serious Implications of the Proposed Revised National TB Control Programme for India	D. Banerjee	1997	VHAI

REPORTS

1.	Hathi Committee Report	1975	GOI
2.	DPCO	1979	Ministry of Chemicals
3.	National Health Policy (with a section on National Drug Policy)	1983	Ministry of Health
4.	NDPDC (National Drugs & Pharmaceutical Development Council Working Groups report and steering committee report)	1984	Ministry of Chemicals
5.	International Consultation of WHO Experts on Rational Drug Use, Nairobi	1985	WHO
6.	Drugging of Asia, Pharmaceuticals and the Third World, Chennai	1985	VHAI, ACHAN IOCU
7.	Drug Industry & the Indian People, Delhi	1981	DSF, FMRAI
8.	Kelkar Committee Report (on drug pricing)	1987	BICP
9.	Drug Policy: Rationalization measures for the	1986	Ministry of

	growth of the drug industry			Chemicals
10.	Lentin Commission Report		1988	Mumbai High Court, Govt. of Maharashtra
12.	Essential Drugs in Primary Health Care, Delhi		1988	NISTADS
13.	Rational Drug Use in Paediatrics, Delhi		1988	AIIMS
14.	National Seminar on Patent Laws		1988	Delhi National Working Groups on Patent Laws
15.	Modifications in Drug Policy		1994	Ministry of Chemicals
16.	DPCO 1994		1995	G.O.I.
17.	Drug Pricing Review Committee under the Chairmanship of Mr D. Chatterjee, Secretary Chemicals Ministry		2001	Ministry of Chemicals
18.	R&D Committee under the Chairmanship of Dr.Mashelkar		2001	CSIR/Ministry of Chemicals
19.	Expert Committee on Comprehensive Examination of Drug Regulatory Issues Including Problems of Spurious Drugs (Mashelkar Committee Report)		Nov. 2003	Ministry of Health & Family Welfare
20.	India Health Report	Rajiv Misra, Rachel Chatterjee, Sujata Rao	2003	Oxford University Press

BOOKS ON DRUGS

	Name of the Book	Author	Year	Publisher
1.	Insult or Injury?	Charles Medawar	1980	Social Audit

2.	Bitter Pills	Dianna Melrose	1982	Oxfam Public Affairs Unit
3.	Drugs & the Third World	Anil Agarwal	1978	Earthscan
4.	There is Gold in them Thar Pills	Alan Klass	1975	Penguin Special
5.	Poor Health, Rich Profits	Tom Heller	1977	Sokesman Books
6.	Limits to Medicine-medical nemesis	Ivan Illich	1980	Pelican Books
7.	The Health of Nations: A north south investigation	Mike Mullar	1982	Faver & Faver Ltd.
8.	Pills against Poverty	Goran Djurfeldt Col. Staffan, Linelbery	1976	Oxford IBH, Pub New Delhi
9.	Drugging of Americas	Milton Silverman	1974	Berkeley University of California Press
10.	Prescription for Death	Milton Silverman	1982	Berkeley University of California Press
11.	Drug Disinformation	Charles Medawar	1980	Social Audit,London
12.	Drug Diplomacy	Charles Medawar & Barbara Freese	1982	Social Audit, London
13.	The People's Pharmacy-I	Joe Graedon	1977	Avon Books, USA
14.	The People's Pharmacy-II	Joe Graedon	1980	Avon Books, USA
15.	Geneva Press Conference on SMON	Organizing Committee on SMON Proceedings	1980	Japan
16.	Drug-induced Sufferings Medical Pharmaceutical & Legal Aspects (Proceedings of the Kyoto Conference)	T. Soda	1980	Excerpta Medica Amsterdam Oxford Princeton
17.	Prescription for Change	Virginia Beardshaw	1983	HAI

18.	Selection of Essential Drugs	WHO, Technical Report Series No.		
		615	1977	WHO
		641	1979	"
		685	1983	"
		686	1985	"
		687	1994	"
		882	1998	"
		895	2000	"
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26.	Pills Policies and Profits	Francis Rolt	1985	War on Want.
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59.	Pharmaceuticals and Drug Pricing in India	S. Srinivasan Dr.Anurag Bhargav		
60.	Whatever happened to health for All by 2000 AD		2000	JSA
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2.	Physicians Desk Reference		58th Edition 2004	Medical Economics Co. Inc.
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4.	The Essential Guide to Prescription		4th Edition 1985	James W. Long Harper & Row Publishers, New York
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6.	WHO model formulary 3rd Model Essential drug list		2003	WHO, 1211, Geneva 27, Switzerland
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4.	HAI News – The newsletter of Health Action International	Frank Fust Place Colombo 4, Srilanka
5.	The Rational Health	Rational Health, Oxfam, 274, Campaign Newsletter, Banbury Road Oxford OX2 7D2 ,UK
6.	Contact (Special issue on Drugs, globalization & health)	Christian Medical Commission, World Council of Churches, 150 Route de Ferney 1211 Geneva, 20, Switzerland
7.	British Medical Journal (South Asian Edition)	MCMRT Medical Journal CTC Building, Manipal – 576104 Karnataka
8.	Essential Drug Monitor	Editor, Essential Drug Monitor WHO, 1211 Geneva 27, Switzerland cdmdoccentre@who.int
9.	Development Dialgoue, Another Development in Pharmaceuticals & National Drug Policy (1985, 1995)	Dag Hammerskjold Foundation, Dag Hammarskjold Centre Ovre Slottsgatan 2 S-752, 20, Uppsala, Sweden
10.	MALAM Medical Lobby for Appropriate Marketing	MALAM 22, Renaissance Arc Adelaide SA 500 Australia
11.	Prescriber International	BP459-75527 Paris, Cedex-II, France
12.	BODHI	Health Action Foundation 254, Lake Town, Kolkata – 700 089
13.	Medico Friend Circle Bulletin	Locost, 1st Floor, Premanand Sahitya Bhawan, Dandia Bazar, Vadodara - 390001
14.	Health for the Millions (Special issues on drugs, 1981)	VHAI B-40 Qutab Institutional Area South of IIT, New Delhi – 110016
15.	Rational therapeutics	CMAI, Plot No. 2, A-3 Local Shopping Centre Janakpuri, New Delhi
16.	Health Action (special issue)	CHAI, 157/6 Staff Rd. 2004 Post Box 2126, Secunderabad–500003

17.	Indian Journal of Medical Ethics	Forum for Medical Ethics Society O-18 'Bhavna', Veer Savarkar Marg, Prabhadevi Mumbai – 400 025
18.	Drug, Disease & Doctor	Drug Action Forum 254 Block B, Lake Town Kolkata – 700 089
19.	Drug Industry	WHO Collaborating Centre on Drug Information Central Drug Research Institute, P.O. Box 173, Lucknow 226 001
20.	Pune Journal of Continuing Health Education (old issues)	Arogya Dakshata Mandal 1913, Sadashiv Peth, Pune – 30
21.	Dear Doctor (old issues)	Rajasthan VHA A-12/B, Mahaveer Udyan Peth Bajaj Nagar Jaipur- 302015 Rajasthan
22.	Rational Drug Bulletin	CDMU Quarterly Bulletin 47/1B, Garcha Road Kolkata – 700 019
23.	ACASH News	Association for Consumers Action on Safety and Health Servants of India Society Building 2nd Floor, 417 Sardar Vallabhbhai Patel Road Mumbai – 400 004

SOURCES OF COMMERCIAL DRUG INFORMATION

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2.	Current Index of Medical Specialities (CIMS)	Biogard Medical Services 640, 10-A Cross, West of Chord Road (II Stage), Bangalore – 560 086
3.	Drug Today	1, Mother Dairy, Commercial Complex Mayur Vihar, Pocket 1, Phase I New Delhi – 91
4.	IDMA Bulletin	Indian Drug Manufacturers 102 B Poonam Chambers Dr A.B. Road, Worli, Mumbai 400018

5.	Chronicle pharmabiz	Pharma India Ltd. 4th Floor, Raj Mahal, 84 Nariman Road Churchgate, Mumbai – 400 020
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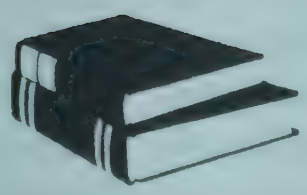
POSTERS		
1.	Drugs for the people or people for the Drug	Drug Action Forum
2.	Profits before people	VHAI
3.	Murder in the name of Medicine	VHAI
4.	Don't judge a medicine by its packaging	VHAI
5.	Ban Bannable Drugs	VHAI
6.	Drugs can be dangerous too	VHAI
7.	Drug Posters	WBVHA
8.	Set of T.B. Posters	VHAI
9.	Drug Posters Medicines & Children	Indian Academy of Paediatrics
VIDEO FILMS ON DRUGS		
1.	In the name of Medicine (Campaign Film)	Media Collective (Hindi version dubbed by late Safdar Hashmi)
2.	Pills, Policies, Profits	VHAI
3.	Anatomy of a Ban: EP Drugs	Doordarshan/Chitrabani
4.	Banned Drugs	Inter News
5.	Rog Purana	DSF
6.	Bangladesh finds the right Prescription	GK
7.	The Pill Jungle	WHO

8.	Healthy Business	German TV
9.	Hard to Swallow	Oxfam
10.	Yellow Haze	Jamia Milia

Editor's Note

Readers are requested to please send details of other books, reports, rational drug campaign material for inclusion and updating of this recommended reading list.



Can I give anti-diarrhoeal drugs to a child with diarrhoea?

These agents, though commonly used, have no practical benefit and are never indicated for the treatment of acute diarrhoea in children. Some of them are dangerous. Products in this category include:

Adsorbents (e.g. kaolin, attapulgite, smectite, activated charcoal, cholestyramine). These drugs are promoted for the treatment of diarrhoea on the basis of their claimed ability to bind and inactivate bacterial toxins or other substances that cause diarrhoea, and their claim to "protect" the intestinal mucosa. None, however, has proven effective or practical in the routine treatment of acute diarrhoea in children.

Antimotility drugs (e.g. loperamide hydrochloride, diphenoxylate with atropine, tincture of opium, camphorated tincture of opium, paregoric, codeine). These opiate or opiate like drugs inhibit intestinal motility and may reduce the frequency of stool passage in adults. However, they do not appreciably decrease the volume of stool in young children. Moreover, they can cause severe paralytic ileus, which can be fatal, and they may prolong infection by delaying elimination of the causative organisms. Sedation may occur at usual therapeutic doses and fatal central nervous system toxicity has been reported for some agents. None of these agents should be given to infants or children with diarrhoea.

Bismuth subsalicylate. Bismuth subsalicylate decreases the number of diarrhoea stools and subjective complaints in adults with travellers' diarrhoea. When given every four hours, it is reported to decrease stool output in children with acute diarrhoea by about 30%. This treatment schedule is, however, rarely practical.

Combinations of drugs. Many products combine adsorbents, antimicrobials, antimotility drugs or other agents. Manufacturers may claim that these formulations are appropriate for various diarrhoeal diseases; however, such combinations are irrational and their cost and side effects are substantially higher than for individual drugs. They have no place in the treatment of diarrhoea in children.

Antiemetics. These include drugs such as prochlorperazine and chlorpromazine, which cause sedation that can interfere with ORT. For this reason antiemetics should never be given to children with diarrhoea. Moreover, vomiting stops when a child is rehydrated.

Cardiac stimulants. Shock in acute diarrhoeal disease is caused by dehydration and hypovolaemia. Correct treatment is rapid IV infusion of a balanced electrolyte solution. The use of cardiac stimulants and vasoactive drugs

(e.g. adrenaline, nicotinamide) is never indicated.

Blood or plasma. Blood, plasma or synthetic plasma expanders are never indicated for children with dehydration due to diarrhoea. These children require the replacement of lost water and electrolytes. These treatments are used, however, for patients with hypovolaemia due to septic shock.

Steroids. Steroids have no benefit and are never indicated.

Purgatives. These can make diarrhoea and dehydration worse; they should never be used.

Source : Frequently asked technical questions, WHO/UNICEF. 2004

GLOSSARY

ABA	Azadi Bachao Andolan
ACASH	Association for Consumer Action on Safety & Health
ADM	Arogya Dakshta Mandal
AIDAN	All India Drug Action Network
Agranulocytosis	A blood disease (often fatal) in which the bone marrow fails to produce white blood cells which fight infection and are essential to life, so that patient easily succumbs to infection and can die.
Allopathy	Western 'modern' medicine.
Analgesic	Drug which reduces pain.
Antagonism	Drugs working against each other in the body.
Anti-pyretic	Drug which reduces fever.
AMREF	African Medical Research & Education Foundation
ARDA	Action for Rational Drugs in Asia
BICP	Bureau of Industrial Costing and Pricing
Brand Name	The trade name given to a drug by its manufacturer.
BMA	British Medical Association
CDSCO	Central Drugs Standard Control Organisation
CED	Centre for Education and Development
CERC	Consumer Education Research Centre

CGSI	Consumer Guidance Society of India
Contraindication	Conditions under which a drug should never be taken.
CDMU	Community Development Medicinal Unit
CMAI	Christian Medical Association of India
CHAI	Catholic Hospital Association of India
CPA	Consumer Protection Act
CU	Consumer Unions
DCC	Drug Consultative Committee
DPCO	Drug Price Control Order
DCGI	Drug Controller General of India
DSPRUD	Delhi Society for Promotion of Rational Use of Drugs
ERDU	Educators for Rational Drug Use
FMRAI	Federation of Medical Representative Association of India
FEDCOT	Federation of Consumer Organizations of Tamil Nadu
FRCH	Foundation for Research in Community Health
FHA	Foundation for Health Action
Generic Name	The accepted scientific name of a drug which is also the non proprietary name or the pharmacopeal name (not the brand name).
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services

ICHI	Independent Commission on Health in India
ICDHI	Independent Commission on Development and Health in India
ICMR	Indian Council of Medical Research
Indication	Recognized illnesses or symptoms for which a drug should be used.
Inflammation	Local swelling of a joint mainly due to accumulation of uric acid etc. Inflammation of a viscera ((e.g. uterus) by various causes, for example infection.
IOCU	International Organization of Consumer Union
ICSSR	Indian Council of Social Sciences Research
IPA	Indian Patent Act
IFPMA	International Federation Pharmaceutical Manufacturer Association
JSA	Jan Swasthya Abhiyan
KSSP	Kerala Sashtra Sahitya Parishad
LOCOST	Low Cost Standard Therapeutics
MFC	Medico Friends Circle
NCAER	National Council for Applied Economic Research
NDA	National Drug Authority
NISTADS	National Institute of Science Technology & Development Studies
NPPA	National Pharmaceutical Pricing Authority
NWGPL	National Working Group on Patent Laws

ORS	Oral Rehydration Solution
ORT	Oral Rehydration Therapy
Osseous	Bony
Over-the-Counter Drugs (OTC)	Drugs which can legally be purchased without a prescription
PIL	Public Interest Litigation
Resistance	Resistance to a drug has occurred when it is no longer effective. This can be either because the drug has been unnecessarily used earlier for trivial illness or because the drug has been given for the correct disease but not in sufficient quantities or for long enough period to kill the germs completely, so that the germs survive in a form which is immune (resistant) to that drug.
SOCHARA	Society for Community Health Awareness Research and Action
Steroids	Steroids are a group of biologically active compounds which are mainly divided into two categories i.e. HORMONAL STEROIDS and NON-HORMONAL STEROIDS. Harmonal Steroids include a greater number of pharmaceutical preparations such as: sex steroids for example ANDROGENS or male sex female ovulatory hormones (estradiol). PROGESTROGEN or female luteal hormone (Progesterone). Non-sex hormones include GLUCOCORTICOIDS (such as Cortisone & Cortisole betamethazone, dexamethazone) and MINERALOCORTICOIDS (such as aldosterone, desoxycorticosterone). Among the non-hormonalsteroids, are Sterols, bile etc
Sub-therapeutic Dose	An amount of medicine too small to have an effect
Therapeutic Dose	The amount of medicine that is required for it to have the desired effect

Titration	To quantify using chemical methods
Toxic	Harmful to the body
TRIPS	Trade Related Intellectual Property Rights
WHO	World Health Organisation
WTO	World Trade Organization

All India Drug Action Network (AIDAN)

AIDAN consists of numerous health, consumer, legal aid and human rights organizations and people's science movements. It is a loose network of academicians, professionals, social activists, individuals and organizations who are deeply concerned about the drug issue and working towards the adoption and implementation of a people oriented Rational Drug Policy in India as a part of a People's Health Policy.

All India Drug Action Network Coordination Committee

1. Academy of Young Scientists
2. Association for Consumer Action on Safety and Health (ACASH), Mumbai
3. Arogya Dakshata Mandal, Pune
4. Azadi Bachao Andolan
5. Catholic Hospital Association of India, Hyderabad
6. Community Development Medicinal Unit, West Bengal
7. Consumer Education and Research Centre, Ahmedabad
8. Consumer Guidance Society of India, Mumbai
9. Drug Action Forum – West Bengal, Kolkata,
10. Drug Action Forum – Karnataka, Bangalore
11. Delhi Science Forum, Delhi
12. Foundation for Health Action, Kolkata, West Bengal
13. Kerala Sashtra Sahitya Parishad, Kerala
14. LOCOST, Baroda
15. Lok Vigyan Sanghatna, Pune
16. Medico Friends Circle, Pune
17. Voluntary Health Association of India, Delhi

Where the mind is without fear
and the head is held high;
where the knowledge is free;
Where the world has not been broken up
into fragments by narrow domestic walls;
Where the words come out from the depth of truth;
Where tireless striving stretches its arms
towards perfection;
Where the clear stream of reason
has not lost its way into the dreary desert sand
of dead habit;
Where the mind is lead forward
by thee into ever-widening thought and action
Into that heaven of freedom,
my Father, let my country awake.

- Rabindranath Tagore

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